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## Preconception care for women with type 1 or type 2 diabetes mellitus: a mixed-methods study exploring uptake of preconception care

*Sarah Earle, Anisah Tariq, Carol Komaromy, Cathy E Lloyd, M Ali Karamat, Jackie Webb and Paramjit S Gill*



***National Institute for  
Health Research***



# Preconception care for women with type 1 or type 2 diabetes mellitus: a mixed-methods study exploring uptake of preconception care

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**Declared competing interests of authors:** none

**Disclaimer:** This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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# Abstract

## Preconception care for women with type 1 or type 2 diabetes mellitus: a mixed-methods study exploring uptake of preconception care

Sarah Earle,<sup>1\*</sup> Anisah Tariq,<sup>1</sup> Carol Komaromy,<sup>1</sup> Cathy E Lloyd,<sup>1</sup> M Ali Karamat,<sup>2</sup> Jackie Webb<sup>2</sup> and Paramjit S Gill<sup>3</sup>

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**Background:** Diabetes mellitus is a global health problem and one of the most common medical conditions in pregnancy. A wide range of modifiable risk factors are associated with diabetes mellitus in pregnancy, and it is widely acknowledged that preconception care (PCC) is beneficial for women with pre-existing diabetes mellitus. However, uptake of PCC services is low.

**Objectives:** To systematically review qualitative research on PCC for women with pre-existing diabetes mellitus of childbearing age, identify facilitators of and barriers to uptake of PCC and establish themes and gaps in knowledge. Through qualitative interviews explore views on the provision of, and facilitators of and barriers to the uptake of, PCC.

**Design:** Mixed methods encompassing a systematic review and qualitative interviews.

**Setting:** Two secondary care sites and 11 primary care sites.

**Participants:** Women of childbearing age with pre-existing type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) of white British or Pakistani origin.

**Interventions:** None.

**Analysis:** A narrative synthesis of the literature using thematic analysis and a thematic analysis of the qualitative interview data using the method of constant comparison.

**Results:** Eighteen qualitative studies were included in the systematic review and a quality appraisal was carried out using relevant criteria for qualitative research appraisal, including a narrative summary of study quality. Twelve interviews with women with pre-existing T1DM or T2DM were carried out. This fell short of the original aim of interviewing 48 women owing to challenges in recruitment, especially in primary care. A synthesis of these data shows that uptake of PCC is influenced by a range of factors, including the complexity of pregnancy planning, the skill and expertise of health professionals who provide care to women with diabetes mellitus, the role of health professionals in the delivery of PCC, and the quality of relationships between women and health professionals.

**Limitations:** Owing to significant challenges with recruitment of participants, particularly in primary care, 12 interviews with women with pre-existing T1DM or T2DM were carried out, which fell short of the a priori sample size.

**Conclusions:** Reconceptualising PCC to place greater emphasis on pregnancy planning, fertility and contraception would lower some of the existing barriers to uptake of care. It is important to clarify who is responsible for the delivery of PCC to women with pre-existing diabetes mellitus and to ensure that the correct expertise is available so that opportunities for advice giving are maximised. Relationships between women and health professionals should be based on a partnership approach that encourages mutual trust and respect, focusing on positive change rather than negative outcomes.

**Future work:** Further research is needed to investigate the views and experiences of stakeholders that commission, design and deliver PCC services for women with pre-existing diabetes mellitus; to explore experiences of women from minority or ethnically diverse backgrounds; to investigate the role of family support in contraception, pregnancy planning and PCC; and to investigate the management of diabetes mellitus in neonatal care and its role in breastfeeding.

**Study registration:** This study is registered as PROSPERO CRD42014015592 and ISRCTN12983949.

**Funding:** The National Institute for Health Research Health Technology Assessment programme.

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# List of abbreviations

|                   |  |        |  |
|-------------------|--|--------|--|
| A level           | Advanced level   | IUD    | intrauterine device  |
| ASSIA             | Applied Social Sciences Index and Abstracts              | NICE   | National Institute for Health and Care Excellence                  |
| BNI               | British Nursing Index                                    | NRES   | National Research Ethics Service                                   |
| CCG               | Clinical Commissioning Group                             | NVQ    | National Vocational Qualification                                  |
| CEMACH            | Confidential Enquiry into Maternal and Child Health      | PCC    | preconception care   |
| CINAHL            | Cumulative Index to Nursing and Allied Health Literature | PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| GCE               | General Certificate of Education                         | R&D    | research and development   |
| GP                | general practitioner                                     | T1DM   | type 1 diabetes mellitus   |
| HbA <sub>1c</sub> | glycated haemoglobin                                     | T2DM   | type 2 diabetes mellitus   |
| HREC              | Human Research and Ethics Committee                      |        |  |



## Plain English summary

**D**iabetes mellitus, a condition in which the amount of sugar (glucose) in the blood is too high, is one of the most common medical conditions in pregnancy. Women with pre-existing diabetes mellitus are at an increased risk of a variety of adverse outcomes including miscarriage, stillbirth, complications during labour and problems with the development of the baby.

The National Institute for Health and Care Excellence has produced preconception care (PCC) guidelines which should help reduce these risks. PCC includes things such as optimising blood glucose levels, folic acid supplementation and supported lifestyle changes (e.g. maintaining a healthy diet). In spite of the benefits of PCC, uptake is low.

This study sets out to explore the facilitators of and barriers to the uptake of PCC by women with pre-existing diabetes mellitus. The study findings, based on a systematic review of 18 qualitative studies and 12 interviews carried out with white British and Pakistani women, reveal four key issues:

1. There is a lack of clarity about what PCC is.
2. There may be a lack of expertise in delivering the core elements of PCC (i.e. pregnancy planning, fertility and contraception).
3. It is not clear who is responsible for delivering PCC to women with diabetes mellitus.
4. Care needs to focus on enabling women to make positive changes rather than treating them as women at risk of failure.





# Scientific summary

## Background

Diabetes mellitus is increasingly recognised as a global epidemic and is one of the most common medical conditions in pregnancy. Rates of diabetes mellitus during pregnancy are rapidly increasing and are seen to be a serious public health concern. These increased rates are mainly due to the rapid rise in type 2 diabetes mellitus (T2DM) and it has been suggested that this is, in turn, associated with an increased prevalence of overweight and obesity in the population, although rates of type 1 diabetes mellitus (T1DM) have also risen, albeit less sharply. In the UK, 1 in 250 pregnancies is affected by diabetes mellitus. Between 1995 and 2012 there was an increase in prevalence of T1DM of 162% and of T2DM of 354%. This research is important now and in the future because rates of diabetes mellitus in pregnancy are high and are likely to increase further both in the UK and globally.

In the UK (and globally), previous research indicates that the majority of women with pre-existing diabetes mellitus do not seek preconception care (PCC). The complications that arise from poorly managed diabetes mellitus during pregnancy, birth and early motherhood are well documented, in that they carry considerable risks to women and children as well as posing an unnecessary financial burden on health services and society. These complications include an increased risk of spontaneous abortion and perinatal mortality, congenital abnormalities and caesarean section.

Pre-existing diabetes mellitus is associated with significantly higher rates of obstetric complications and maternal and neonatal morbidity and mortality. Previous research indicates that improving the uptake of PCC for women with pre-existing diabetes mellitus would add significant anticipated value, such as a reduction in adverse outcomes, to the health service provision already in place. A full spectrum of modifiable risk factors are associated with diabetes mellitus, which means that women with diabetes mellitus of childbearing age stand to benefit from PCC. These modifiable risk factors include optimisation of blood glucose levels, folic acid supplementation and supported lifestyle changes. Preconception services provide advice and support to enable positive behaviour change, which can have a positive impact on pregnancy, childbirth and early parenting. There is significant clinical evidence from the UK and other countries to suggest that PCC can play an important role in risk factor modification.

Policy imperatives, such as the National Institute for Health and Care Excellence (NICE) guidelines and quality standards, strongly recommend PCC for women with pre-existing diabetes mellitus. There is also general agreement in the literature on the practical arrangements for PCC, including the role of multidisciplinary care teams. In spite of these recommendations and practices, PCC has been described as 'a black hole with services struggling to provide accessible and timely services' (Hawthorne G, Modder J. *Maternity services for women with diabetes in the UK. Diabetic Medicine* 2002;**19**:50–55) and, more recently, researchers have called for a 'fresh look' at service provision. The proposed project provides this fresh look to inform preconception service provision and delivery that could enable more women with pre-existing diabetes mellitus to access care that could have a significant impact on health and on the disease burden.

## Aims and objectives

The project aimed to:

- understand why women with diabetes mellitus of childbearing age do, or do not, access PCC, with a view to informing services
- investigate the views of staff and stakeholders to explore existing and future provision of PCC.

The objectives of this project were to:

- systematically review the descriptive research on PCC for women with diabetes mellitus of childbearing age and establish themes and gaps in knowledge
- identify views on the provision of, and facilitators of and barriers to the uptake of, PCC through qualitative work.

## Design and methods

### *Design*

The project was designed in several phases to generate new insights in order to understand the facilitators of and barriers to uptake of PCC for women with pre-existing diabetes mellitus. A systematic review of the literature was carried out to generate a narrative synthesis that would identify themes and gaps in existing knowledge. Qualitative interviews with women were also conducted in order to explore issues relating to pregnancy planning, diabetes mellitus and uptake of PCC.

### *Setting*

Given that women with pre-existing diabetes mellitus receive care across primary and secondary care settings, the qualitative interviews were based in two main settings: (1) 11 general practices in the Sandwell and West Birmingham Clinical Commissioning Group and (2) two PCC and antenatal clinics in the Heart of England NHS Foundation Trust.

### *Participants*

The participants comprised women with pre-existing diabetes mellitus of childbearing age and of either white British or Pakistani origin. Women with pre-existing mental health issues and women with gestational diabetes mellitus were excluded from the study.

### *Analysis*

For the systematic review of the descriptive literature, two main approaches were used to analyse the studies. First, each study was summarised by extracting the following details from the study: study aim, participant characteristics, method of data collection, method of data analysis and study context. Other data were extracted as part of the quality appraisal process. Second, the studies were imported into the qualitative data analysis software program NVivo 11 for Mac (QSR International, Warrington, UK) and an inductive thematic analysis was carried out. The purpose of carrying out the thematic analysis was to produce a narrative synthesis of the selected studies in order to identify common themes, gaps in knowledge and to generate new knowledge.

All interviews were audio-recorded with the permission of respondents. Anonymised transcripts were imported into NVivo. NVivo was used to support the analysis of the data using thematic analysis and the method of 'constant comparison'. A 'factual' profile of each participant was also written and reported to capture some of the complexity of individual cases.

Each data set was subjected to both separate and integrated analysis to enable identification and comparison of significant themes between and within the reviewed literature and the interviews with women.

## Ethics approval

A favourable ethics opinion was granted from The Open University Human Research and Ethics Committee (HREC) and the South Central – Berkshire National Research Ethics Service Committee (reference 15/SC/0026). NHS research and development (R&D) permissions were also gained from the lead site for the project which issued relevant letters of approval and access.

## Patient and public involvement

Service users were involved in the design of the study, the ethics application and in the design of all of the patient information forms and consent forms. Lay readers have been involved in reviewing the final project report and the plain English summary.

## Research findings and results

For the systematic review, 496 records were identified through database searching and an additional 12 identified through other sources. Databases searches were performed in November 2014 and December 2015, from 1980 to 2015, and included Academic Search Complete, Applied Social Sciences Index and Abstracts (ASSIA), British Nursing Index (BNI), Cumulative Index to Nursing and Allied Health Literature (CINAHL), The Cochrane Library, ProQuest Dissertations & Theses Database, Interim, Maternity and Infant Care, MEDLINE, PubMed, ScienceDirect, Scopus and Web of Science. After removing duplicates, 472 records remained and were screened by two reviewers. Following screening, 49 full-text articles were read to assess for eligibility. Eighteen studies were included in the systematic review and qualitative synthesis, and a narrative summary of study quality was included.

It was the original intention of the project to interview up to 48 women with pre-existing diabetes mellitus of childbearing age about their views and experiences of PCC. Following considerable difficulties with recruitment, especially in primary care, 12 women were interviewed as part of the study. Nine of the participants had T1DM and three had T2DM. Three participants were Pakistani in origin and nine were white British.

In analysing the data derived from the systematic review and the in-depth interviews, four key findings emerged.

1. There is a lack of clarity over what PCC for women with diabetes mellitus comprises and how it is perceived.
2. On the basis of this and following a reconceptualisation of PCC, pregnancy planning, fertility and contraception must be core elements of that care. This raises issues about the required levels of expertise needed for practitioners to deliver that care effectively.
3. There is a lack of clarity about who is responsible for the delivery of PCC to women with diabetes mellitus and, if a reconceptualised model of PCC has pregnancy planning, fertility and contraception at its core, then that impacts significantly on whose responsibility its delivery becomes and the required levels of expertise needed to deliver good care. Further distinctions can be made between women with T1DM and T2DM, as their care tends to be managed in different settings.
4. The quality of care delivery is dependent on a form of care that is based on partnership working, is woman centred and individualised, and values the need for continuity. Such care needs to be about enabling women to make changes that are positive rather than treating them as women at risk of failure.

## Conclusions

The number of women interviewed in this study is not dissimilar to other similar qualitative studies in that sample sizes, by their nature, tend to be modest. However, the number of interviews carried out did fall short of the original intentions of the project. That said, the qualitative findings are generally supportive of the findings of the systematic review.

The study findings indicate that reconceptualising PCC to place a greater emphasis on pregnancy planning, fertility and contraception would ameliorate some of the existing barriers to uptake of care. Clarification on

who is responsible for the delivery of PCC to women with pre-existing diabetes mellitus is required, as is ensuring that the correct expertise is available so that opportunities for giving information are maximised. Relationships between women and health professionals should be based on a partnership approach that encourages mutual trust and respect focusing on positive change, rather than negative outcomes.

Further research, in order of priority, should focus on:

- investigation of the views of stakeholders involved in the commissioning, design and delivery of PCC services for women with pre-existing diabetes mellitus
- further investigation of the views and experiences of minority and ethnically diverse groups, including the experiences of women who do not speak English
- the role of family and other support in pregnancy planning and PCC
- the management of diabetes mellitus in neonatal care and its role in breastfeeding.

## Registrations

This study is registered as PROSPERO CRD42014015592 and ISRCTN12983949.

## Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

# Chapter 1 Introduction and background

Diabetes mellitus is increasingly recognised as a global epidemic and is one of the most common medical conditions in pregnancy.<sup>1</sup> Rates of diabetes mellitus during pregnancy are rapidly increasing and are viewed as a serious public health concern. These increased rates are mainly due to the rapid rise in type 2 diabetes mellitus (T2DM), and it has been suggested that this is associated with an increased prevalence of overweight and obesity in the population, although rates of type 1 diabetes mellitus (T1DM) have also risen, albeit less sharply.<sup>2</sup> In the UK, 1 in 250 pregnancies is affected by diabetes mellitus. Diabetes UK estimated that in 2010 approximately 8000 women living with diabetes mellitus in England and Wales became pregnant.<sup>3</sup> Between 1995 and 2012 the prevalence of T1DM increased by 162% and that of T2DM increased by 354%.<sup>4</sup>

The complications that arise from poorly managed diabetes mellitus during pregnancy, birth and early motherhood are well documented, in that they carry considerable risks to women and children, as well as posing an unnecessary financial burden on health services and on society.<sup>5</sup> A report from the Confidential Enquiry into Maternal and Child Health (CEMACH), which focused on women with pre-existing diabetes mellitus, highlighted a fivefold increase in stillbirths, a threefold increased risk of perinatal mortality and a twofold increased risk of congenital abnormalities.<sup>6</sup> Preterm delivery rates were more than five times higher in women with diabetes mellitus than in women without diabetes mellitus and caesarean section rates nearly three times higher.

Research suggests that women who develop gestational diabetes mellitus also have an increased risk of morbidity and mortality. For example, one study<sup>7</sup> found that gestational diabetes mellitus was a predictor of adverse maternal outcomes including hypertension and such neonatal outcomes as prematurity, low Apgar scores and perinatal mortality. However, adverse outcomes are more significant for women with pre-existing diabetes mellitus than for those who develop diabetes mellitus in pregnancy (gestational). Given these increased risks, it follows that preconception care (PCC) for women with existing diabetes mellitus is vital in order to improve health outcomes, and this was central to the aims of this study. Although gestational diabetes mellitus is not the focus of this study, it is worth noting that appropriate pregnancy planning and PCC is relevant to all women of childbearing age as women who develop gestational diabetes mellitus are at an increased risk of developing T2DM later in life.<sup>8</sup>

Previous research has shown that improving the uptake of PCC for women with pre-existing diabetes mellitus would add significant anticipated value, such as a reduction in adverse outcomes, to the health service provision already in place.<sup>6,9</sup> Diabetes mellitus is associated with a full spectrum of modifiable risk factors, which means that women with diabetes mellitus of childbearing age stand to benefit from PCC. These modifiable risk factors include optimisation of blood glucose levels, folic acid supplementation and supported lifestyle changes. Preconception services provide advice and support to enable a positive behaviour change, which can have a positive impact on pregnancy, childbirth and early parenting. There is significant clinical evidence from the UK and other countries to suggest that PCC can play an important role in risk factor modification.

In the UK (and elsewhere) previous research indicates that the majority of women with pre-existing diabetes mellitus do not seek PCC. In 2005, the CEMACH<sup>9</sup> estimated that only 34% of women with diabetes mellitus accessed PCC, and this level of care has been described as suboptimal.<sup>4</sup>

Although definitions of PCC are wide-ranging, in practical terms, its central tenets typically include genetic and family history risk assessment, immunisation, vitamin supplementation (especially folic acid), smoking cessation advice, and advice on alcohol intake, weight management, diet and exercise. Although such a package of care might well be useful for all women, it is those with pre-existing health concerns who stand to benefit the most. Diabetes mellitus comes within the remit of PCC as a 'full spectrum of modifiable risk factors' that can be addressed and managed.<sup>10</sup> The most pertinent goal for women with diabetes mellitus is

to achieve and manage a steady level of blood glucose control.<sup>11</sup> Ideally, this needs to be achieved prior to pregnancy because, by the time a pregnant woman makes it to her first early prenatal visit, most fetal organs have already been formed.<sup>12</sup>

Policy imperatives such as the National Institute for Health and Care Excellence (NICE) guidance and quality standards strongly recommend PCC for women with pre-existing diabetes mellitus. In 2011, PCC was included as part of the NICE *Diabetes in Adults (Quality Standard)*.<sup>13</sup> The revised NICE guidelines on *Diabetes in Pregnancy: Management from Preconception to the Postnatal Period* published in 2015<sup>14</sup> makes specific recommendations for PCC. *Box 1* outlines the revised NICE recommendations.

The literature on PCC reveals a consensus that its delivery to women with all types of diabetes mellitus remains an area in which more work needs to be done; it is, according to one study, 'a black hole with services struggling to provide accessible and timely services'.<sup>15</sup> In the literature, it was also widely agreed that the goals of the *St Vincent Declaration on diabetes care and research in Europe*,<sup>16</sup> which set a 5-year European-wide target for achieving pregnancy outcomes in women with diabetes mellitus similar to those of women without diabetes mellitus, had not yet been achieved.<sup>17</sup> Furthermore, on an international and national level, there is an inconsistency in its approach and recommendations.<sup>18</sup>

The findings of this study address the need to understand why women with pre-existing diabetes mellitus of childbearing age do, or do not, access PCC, with a view to informing services. There are few qualitative studies that focus on women's experiences of PCC. Refocusing preconception research agendas on the experiences of women and the views of those involved in their care, allows for a fuller and more nuanced exploration of the provision and experiences of PCC for women with pre-existing diabetes mellitus.

This report includes data from two sources: (1) the findings of a systematic review of the descriptive literature that draws on both the experiences and perceptions of women and the health-care professionals who provide their care and (2) the findings from one-to-one interviews with white British and Pakistani women of childbearing age with pre-existing diabetes mellitus.

The project aimed to:

- understand why women with diabetes mellitus of childbearing age do, or do not, access PCC, with a view to informing services
- investigate the views of staff and stakeholders to explore existing and future provision of PCC.

#### BOX 1 National Institute for Health and Care Excellence recommendations on PCC

- Seek to empower women by providing information about outcomes and risks for mother and baby.
- Explain to women the importance of planning pregnancy and the role of contraception.
- Offer advice on diet, dietary supplements and body weight, especially folic acid supplementation to prevent neural tube defects.
- Offer increased monitoring of blood glucose and ketones in the preconception period.
- Target blood glucose and HbA<sub>1c</sub> levels in the preconception period.
- Discontinue medicines for diabetes mellitus and complications of diabetes mellitus that may not be safe before and during pregnancy.
- Remove barriers to PCC and offer information to women at each contact and within a supportive environment.
- Offer women education and advice, prior to discontinuing contraception.
- Offer retinal assessment in the preconception period.
- Offer renal assessment in the preconception period.

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HbA<sub>1c</sub>, glycated haemoglobin.

The objectives of this project were to:

- systematically review the descriptive research on PCC for women with diabetes mellitus of childbearing age and establish themes and gaps in knowledge
- identify views on the provision of, and facilitators of and barriers to the uptake of, PCC through qualitative work.

This research is important now and in the future because diabetes mellitus is one of the most common medical conditions in pregnancy and can lead to significant complications for women and babies. Rates of diabetes mellitus in pregnancy are high and are likely to increase further both in the UK and globally. However, given the range of modifiable risk factors, complications in pregnancy can be reduced. Uptake of PCC by women is currently low and considered to be suboptimal. This study has explored the facilitators of and barriers to the uptake of PCC.





## Chapter 2 Systematic review methods

This section outlines the methods used to carry out the systematic review of the literature concerning the facilitators of and barriers to uptake of PCC for women with pre-existing diabetes mellitus. The project sought to explore the experiences and views of women with pre-existing diabetes mellitus of childbearing age as well as the experiences and views of practitioners involved in the care of such women. This section outlines the review question and inclusion criteria, search strategy, approach to quality appraisal and data analysis.

### Review question and inclusion criteria

This systematic review set out to consider the following questions:

- (a) Who is involved in the delivery of PCC and what are the demographic and social factors that influence uptake?
- (b) What PCC is currently provided and what are the views on the implementation of guidelines and recommendations?
- (c) Where is PCC most likely to be provided, what are the prevailing views on this and how does this affect uptake?
- (d) When do women access PCC, when is this service offered and how does this influence uptake?
- (e) Why do some women access PCC and others not and what influences this?

Studies were defined as eligible for inclusion in the review if they met the following criteria (see 'in/out' forms in *Appendices 1* and *2*).

- They presented descriptive data in terms of method, analysis and presentation of results.
- They discussed PCC for women with pre-existing diabetes mellitus in isolation or within a more general discussion of diabetes mellitus in pregnancy.
- They included women (or referred to women) with pre-existing diabetes mellitus aged between 18 and 45 years.

Studies that were not published in English were excluded as there was no means to translate these within the resources of the study.

### Search strategy

An information specialist within The Open University Library Service was consulted to assist in the development of the search strategy. This meant that the correct databases were included; the specialist also advised on the use of appropriate search terms. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used.<sup>19</sup>

One researcher (AT) conducted the literature search in November 2014 and then updated the search in December 2015. The 13 databases searched were Academic Search Complete; Applied Social Sciences Index and Abstracts (ASSIA); British Nursing Index (BNI); Cumulative Index to Nursing and Allied Health Literature (CINAHL); The Cochrane Library; ProQuest Dissertations & Theses Database; Interim; Maternity and Infant Care; MEDLINE; PubMed; ScienceDirect; Scopus; and Web of Science. Years of inclusion were 1980–2015.

The search terms used are presented in *Box 2*.

**BOX 2** Search terms used for the systematic review

('diabetes mellitus' OR diabetes OR 'type 1 diabetes' OR 'type 2 diabetes' OR 'pre-existing diabetes' OR 'preexisting diabetes' OR 'pre-gestational diabetes' OR 'pre-gestational diabetes').

AND ('preconception care' OR 'pre-conception care' OR 'pre-pregnancy care' OR 'prepregnancy care' OR 'preconception services' OR 'pre-conception services' OR 'pre-pregnancy advice' OR 'prepregnancy advice' OR 'preconception advice' OR 'pre-conception advice').

AND (pregnancy OR pregnancies OR 'pregnancy in diabetics' OR 'pregnancy in diabetes').

AND (advice OR attitude OR barrier OR belief OR behaviour OR behavior OR communication OR counselling OR counseling OR decision OR 'decision making' OR experience OR knowledge OR perception OR relationship OR guidelines OR guidance OR recommendations OR education OR advantages OR disadvantages OR experience OR policy OR management).

AND ('focus group' OR interview OR interviews OR descriptive OR qualitative OR consultations).

Manual searches in relevant journals were also conducted using their websites to ensure that any relevant papers not indexed could be identified. These journals were *Sociology of Health & Illness*, *Midwifery*, *Women's Studies International Forum*, *British Journal of Midwifery* and *Journal of Midwifery and Women's Health*. Manual searches using the citations of the selected studies were also carried out in order to identify further papers that were not indexed in the databases. A search for relevant grey literature was carried out by searching the NHS evidence database, Google (Google Inc., Mountain View, CA, USA) (first 100 hits), Google Scholar (Google Inc.) (first 100 hits) and specialist sites that might contain information on PCC for women with diabetes in pregnancy (Diabetes UK,<sup>20</sup> Foresight<sup>21</sup> and the National Childbirth Trust<sup>22</sup>).

## Study selection and quality appraisal

Two researchers (AT and SE) met on a regular basis to discuss the progress of the literature review. AT conducted the database search and listed the initial citations, removing any duplicates. Manual searches through other sources were carried out by both AT and SE. AT read the titles and abstracts and identified any papers that did not meet the inclusion criteria; SE checked the titles and abstracts independently and agreed that these papers did not meet the criteria for inclusion. AT shortlisted the eligible sources and downloaded them. AT and SE individually assessed the sources separately and then met to discuss their reasoning for inclusion and exclusion. Any discrepancies were dealt with between them, with adequate reasoning and bearing the objectives of the literature review in mind and with use of the 'in/out' tool (see *Appendices 1* and *2*). There were no differences in judgement requiring discussion with a third reviewer. After assessing for eligibility, some sources were removed before establishing the final list of sources for inclusion in the systematic review.

Quality appraisal was carried out by AT and SE following the criteria described by Walsh and Downe.<sup>23</sup> Following a review of existing quality appraisal criteria for qualitative research,<sup>24,25</sup> Walsh and Downe<sup>23</sup> provided a different set of criteria for qualitative research appraisal that are intended to be used reflexively and in the spirit of the qualitative research tradition. In this context, they suggest using criteria to give an indication of research quality without relying on checklists, ratings or quality scores. Using this approach, the quality appraisal for each study is detailed in *Chapter 3* (see *Table 2*). Data were extracted on the scope and purpose of study, study design, sampling strategy, analysis, interpretive framework, issues relating to reflexivity, issues relating to ethics, the relevance and transferability of the study, and a narrative summary of the study quality.

## Data analysis

Two main approaches were used in order to analyse the data derived from the selected studies, summary and synthesis. First, each study was summarised by extracting the following details from the study: study aim, participant characteristics, method of data collection, method of data analysis and study context. Other data were extracted as part of the quality appraisal process already described and reported above. The summary of the studies (carried out by AT and SE independently) is presented in a summary table in *Chapter 3* (see *Table 3*).<sup>26–43</sup>

The original intention was to analyse the selected studies according to the five key review questions described in *Review question and inclusion criteria*. However, it soon became clear that it would be difficult to analyse the studies on that basis as many did not address these questions directly and/or were organised differently. Instead, a more inductive thematic analysis was carried out. The purpose of carrying out the thematic analysis was to produce a narrative synthesis of the selected studies in order to identify common themes, gaps in knowledge and to generate new knowledge.

All of the selected studies were read and reread three times each and then saved as sources in NVivo 11 for Mac (QSR International, Warrington, UK), a qualitative data analysis software package. Each source (study) was analysed inductively bearing in mind the need to understand the facilitators of and barriers to uptake of PCC. This process of coding created 136 separate codes (or nodes) within NVivo. Using a process of constant comparison, or 'dynamic going back and forth',<sup>44</sup> the codes were then reviewed and some codes were collapsed into one another because of similarities between them. After this process was carried out, 116 codes remained. The codes were then grouped together into analytical categories. The codes and categories were compared in order to ensure that all codes were included and that they were robust. At this stage some of the emergent categories were collapsed into other categories and some codes were moved between categories. In the final stage of analysis, the categories were grouped into themes and subthemes.



## Chapter 3 Systematic review findings

In this section, the studies identified for inclusion in the systematic review are described and summarised in *Table 2*. The findings of the review are also discussed and the main themes and subthemes are outlined in *Table 4*.

### Results of the literature search

The breakdown of the results for each database is given in *Table 1*.

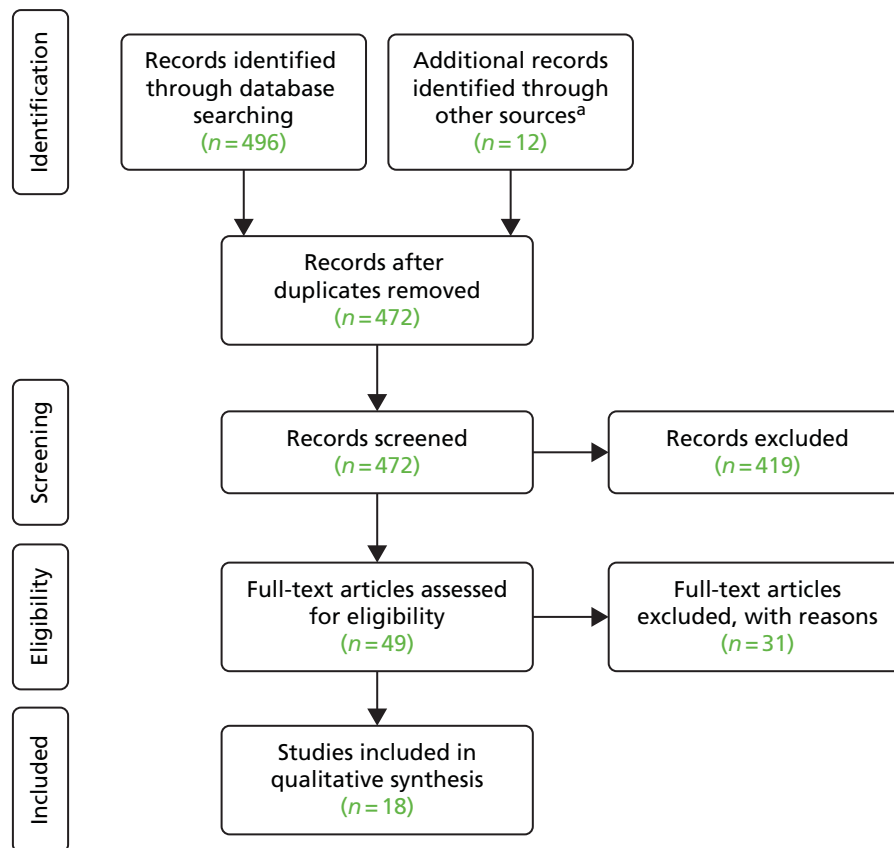
As noted in *Chapter 2*, AT and SE met on a regular basis to discuss the literature review. AT conducted the database search and listed the 496 papers, of which 36 were duplicates and were removed. Twelve papers were identified through other sources, resulting in a total of 472 papers. AT read the 472 titles and abstracts and identified 419 papers that did not meet the inclusion criteria; SE checked the titles and abstracts independently and agreed that these papers did not meet the criteria for inclusion. A total of 49 papers were related to the research question. AT shortlisted the 49 eligible articles and downloaded them. AT and SE individually assessed the 49 articles separately and then met to discuss their reasoning for inclusion and exclusion. Any discrepancies were dealt between them, with adequate reasoning and bearing the objectives of the literature review in mind and with use of the 'in/out' tool (see *Appendices 1* and *2*). There were no differences in judgement requiring discussion with a third reviewer. Thirty-one papers were excluded after being fully read. A final 18 studies were included in the systematic review, two of which were theses and 16 were journal articles. PRISMA reporting guidelines<sup>19</sup> have been followed and *Figure 1* shows the systematic review process.

### Summary of included studies

Eighteen studies met the inclusion criteria for this systematic review; 16 of these were journal articles and two were theses, providing data for 374 women and 642 key professional stakeholders. The full citations of the studies that were excluded from the review are given in *Appendix 3*.

**TABLE 1** Results of database search for systematic review

| Name of database                         | Number of papers found |
|--|------------------------|
| Academic Search Complete                 | 10                     |
| ASSIA                                    | 2                      |
| BNI                                      | 3                      |
| CINAHL                                   | 21                     |
| The Cochrane Library                     | 2                      |
| ProQuest Dissertations & Theses Database | 1                      |
| Intermid                                 | 17                     |
| Maternity and Infant Care                | 0                      |
| MEDLINE                                  | 2                      |
| PubMed                                   | 208                    |
| ScienceDirect                            | 185                    |
| Scopus                                   | 27                     |
| Web of Science                           | 18                     |



**FIGURE 1** Flow diagram showing systematic review process. a, Two papers identified in November 2015.

Of the 18 studies that were included (which are described in detail in *Table 2*), 13<sup>26–28,30–34,37,38,40,42,43</sup> addressed the experiences and perceptions of women only, four<sup>29,35,36,39</sup> addressed the experiences and perceptions of health-care practitioners only and one study<sup>41</sup> addressed the experiences and perceptions of women and practitioners. It is of note that there are relatively few studies that have explored the views of practitioners responsible for providing care to women with diabetes mellitus in pregnancy. The largest majority of studies ( $n = 9$ )<sup>30,33,34,36,37,40–43</sup> were based in a UK context, six<sup>27–29,31,35,39</sup> were based in the USA and one study each was based in Australia,<sup>32</sup> Ireland<sup>38</sup> and Sweden.<sup>26</sup> The study based in Australia<sup>32</sup> is distinct because it focused specifically on the experiences of women living in rural and relatively isolated communities. Of the 14 studies that addressed the experiences or perceptions of women, eight<sup>27,28,31,33,37,38,41,42</sup> included both women with T1DM and those with T2DM and six<sup>26,30,32,34,40,43</sup> included only women with T1DM. There were no studies that focused solely on the experiences of women with T2DM. The studies varied considerably in size, reflecting the fact that some studies adopted a mixed-methods approach. The number of participants included in the studies reporting on women's experience ranged from only seven,<sup>43</sup> to 107.<sup>41</sup> A wider range is seen in the studies reporting the experiences of health-care practitioners, which ranged from 15<sup>36</sup> to 510 practitioners.<sup>39</sup> Participants were predominantly recruited from secondary care but some studies reported use of other settings. Twelve studies<sup>26,30,31,33,34,36–38,40–43</sup> were located in secondary care and only one<sup>36</sup> in both primary and secondary care. The study that recruited from primary care did so in order to recruit general practitioners (GPs) to the study. Six studies<sup>27–29,32,35,39</sup> were located in other settings, such as the community or online, or drew on alternative methods of recruitment. Methods of data collection varied, but 14<sup>27–30,32,34–40,42,43</sup> out of the 18 studies used a single method, whereas the remaining four studies used mixed methods.<sup>26,31,33,41</sup> Interviews were the most highly used method of data collection ( $n = 10$ )<sup>26,30–34,36,37,40,41</sup> followed by focus groups ( $n = 7$ ),<sup>26–29,33,35,42</sup> questionnaires ( $n = 3$ ),<sup>31,39,41</sup> analysis of records ( $n = 2$ )<sup>31,41</sup> and participative workshops ( $n = 1$ ).<sup>38</sup> The selected studies reported using eight different analytical approaches with thematic analysis being the most common. Six studies<sup>28,30,32,34,35,41</sup> reported using thematic analysis. Content analysis was the next most commonly used method of data analysis.<sup>29,31,42</sup> The remaining nine studies reported using the following approaches to data analysis: framework analysis,<sup>36,37</sup> interpretive,<sup>26,33</sup> phenomenological,<sup>40,43</sup> cluster analysis,<sup>39</sup> grounded theory<sup>27</sup> and participant-generated 'web of ideas'.<sup>38</sup>

TABLE 2 Summary of the characteristics of the included studies

| Study reference  | Aims of study   | Participants   | Method of data collection   | Method of analysis  | Setting and context; country     |
|--|---|--|---|---|----------------------------------|
| Berg M, Sparud-Lundin C. Experiences of professional support during pregnancy and childbirth – a qualitative study of women with type 1 diabetes. <i>Diabetic Med</i> 2009; <b>9</b> :27 <sup>26</sup>   | To explore the need for and experience of professional support during pregnancy and childbirth among women with T1DM  | 23 parous Swedish-speaking women with T1DM   | Focus groups; interviews  | Lifeworld research approach using interpretive analysis                 | Secondary care; Sweden           |
| Chuang CH, Velott DL, Weisman CS. Exploring knowledge and attitudes related to pregnancy and preconception health in women with chronic medical conditions. <i>Matern Child Health J</i> 2010; <b>14</b> :713–19 <sup>27</sup>   | To explore pregnancy and preconception health knowledge and attitudes in the context of specific chronic maternal diseases  | 72 women of mixed parity with T1DM or T2DM ( <i>n</i> = 16), hypertension and obesity  | Focus groups  | Modified grounded theory  | Media advertisement, flyers; USA |
| Collier SA, Mulholland C, Williams J, Mersereau P, Turay K, Prue C. A qualitative study of perceived barriers to management of diabetes among women with a history of diabetes during pregnancy. <i>J Womens Health</i> 2011; <b>20</b> :1333–9 <sup>28</sup>              | To explore barriers to glycaemic control before, during and after pregnancy   | 35 white, black and Hispanic women with pre-existing and gestational diabetes mellitus | Focus groups  | Thematic analysis   | Community; USA                   |
| Devido J. <i>Exploring the Role of the Parish Nurse in Providing Diabetes Education and Preconception Counseling to African American Women Using a Community-Engaged Mixed Methods Approach</i> . PhD thesis. Pittsburgh: University of Pittsburgh, PA; 2014 <sup>29</sup> | To explore the experiences of parish nurses in providing diabetes mellitus education and preconception counselling to women (especially African American women) with T1DM and T2DM                                | 48 parish nurses   | Focus groups  | Qualitative content analysis combined with descriptive measure analysis | Community; USA                   |
| Griffiths F, Lowe P, Boardman F, Ayre C, Gadsby R. Becoming pregnant: exploring the perspectives of women living with diabetes. <i>Br J Gen Pract</i> 2008; <b>58</b> :184–90 <sup>30</sup>  | To explore how identity was linked to the improvement and deterioration of blood glucose control in women with T1DM and to explore women's accounts of their journeys to becoming pregnant while living with T1DM | 15 pregnant women with T1DM  | Semistructured interviews   | Comparison of women's accounts and thematic analysis                    | Secondary care; UK               |
| Holing EV, Beyer CS, Brown ZA, Connell FA. Why don't women with diabetes plan their pregnancies? <i>Diabetes Care</i> 1998; <b>21</b> :889–95 <sup>31</sup>  | To determine why women with diabetes mellitus do not plan their pregnancies   | 85 white and Hispanic women with diabetes mellitus                                     | Interviews; self-administered questionnaires; medical record review | Quantitative and qualitative analysis; content analysis                 | Secondary care; USA              |

continued



TABLE 2 Summary of the characteristics of the included studies (continued)

| Study reference   | Aims of study  | Participants  | Method of data collection              | Method of analysis               | Setting and context; country                           |
|---|--|---|--|----------------------------------|--|
| King R, Wellard S. Juggling type 1 diabetes and pregnancy in rural Australia. <i>Midwifery</i> 2009; <b>25</b> :126–33 <sup>32</sup>  | To explore the experiences of women with T1DM while preparing for pregnancy and childbirth; to describe women's engagement with, and expectations of, health-care providers; to highlight potential service and informational gaps | 7 parous women with T1DM  | Interviews                             | Thematic analysis                | Local diabetes mellitus services and online; Australia |
| Lavender T, Platt MJ, Tsekiri E, Casson I, Byrom S, Baker L, Walkinshaw S. Women's perceptions of being pregnant and having pregestational diabetes. <i>Midwifery</i> 2010; <b>26</b> :589–95 <sup>33</sup>                             | To explore the experiences of white British and South-East Asian women with T1DM and T2DM, and the perceived impact of diabetes mellitus on their reproductive health  | 22 pregnant and non-pregnant white, South-East Asian and black African women of mixed parity with T1DM (n = 15) or T2DM (n = 7) | Focus groups and one-to-one interviews | Interpretive analytical approach | Secondary care; UK                                     |
| McCorry NK, Hughes C, Spence D, Holmes VA, Harper R. Pregnancy planning and diabetes: a qualitative exploration of women's attitudes toward preconception care. <i>J Midwifery Womens Health</i> 2012; <b>57</b> :396–402 <sup>34</sup> | To explore the attitudes about pregnancy and PCC seeking in women with T1DM  | 14 women with T1DM  | In-depth semistructured interviews     | Thematic analysis                | Secondary care; UK                                     |
| Mersereau P, Williams J, Collier SA, Mulholland C, Turay K, Prue C. Barriers to managing diabetes during pregnancy: the perceptions of health care practitioners. <i>Birth</i> 2011; <b>38</b> :142–9 <sup>35</sup>                     | To investigate the concerns of health-care practitioners who care for women with a history of diabetes mellitus during pregnancy and their perceptions of attitudes and barriers to achieving good glycaemic control               | 53 health-care practitioners  | Focus groups                           | Thematic analysis                | List of practitioners purchased from private firm; USA |
| Mortagy I, Kielmann K, Baldeweg SE, Modder J, Pierce MB. Integrating preconception care for women with diabetes into primary care: a qualitative study. <i>Br J Gen Pract</i> 2010; <b>60</b> :815–21 <sup>36</sup>                     | To explore the perspectives of GPs and secondary health professionals on the role of GPs in delivering PCC to women with diabetes mellitus   | 8 GPs and 7 secondary care professionals  | Semistructured interviews              | Framework approach               | Primary care and secondary care; UK                    |

| Study reference   | Aims of study   | Participants  | Method of data collection                       | Method of analysis  | Setting and context; country     |
|---|---|---|---|---|----------------------------------|
| Murphy HR, Temple RC, Ball VE, Roland JM, Steel S, Zill-E-Huma R, et al. Personal experiences of women with diabetes who do not attend pre-pregnancy care. <i>Diabet Med</i> 2010; <b>27</b> :92–100 <sup>37</sup>                              | To explore the views of women who did not attend PCC  | 29 white European and Asian pregnant women of mixed parity with T1DM (n = 21) or T2DM (n = 8) diabetes mellitus | Semistructured interviews                       | Framework approach  | Secondary care UK                |
| <sup>a</sup> O'Higgins S, McGuire BE, Mustafa E, Dunne F. Barriers and facilitators to attending pre-pregnancy care services: the ATLANTIC-DIP experience. <i>Diabet Med</i> 2014; <b>31</b> :366–74 <sup>38</sup>                              | To understand why women with diabetes mellitus choose to attend PCC and to identify perceived barriers  | 14 nulliparous and parous white women with T1DM (n = 10) or T2DM (n = 4)  | Participative research process using workshops  | Participant-created 'webs of ideas'                         | Secondary care; Ireland          |
| Power ML, Wilson EK, Hogan SO, Loft JD, Williams JL, Mersereau PW, Schulkin J. Patterns of preconception, prenatal and postnatal care for diabetic women by obstetrician-gynecologists. <i>J Reprod Med</i> 2013; <b>58</b> :7–14 <sup>39</sup> | To assess barriers to and quality of care received by women with diabetes mellitus from obstetricians and gynaecologists                            | 510 health-care practitioners   | Postal questionnaires                           | SPSS 16.0 (SPSS Inc, Chicago, IL, USA) and cluster analysis | Members of research network; USA |
| Richmond J. Coping with diabetes through pregnancy. <i>Br J Midwifery</i> 2009; <b>17</b> :84–91 <sup>40</sup>  | To explore how identity was linked to the improvement and deterioration of blood glucose control in women with T1DM                                 | 11 parous women with T1DM   | Interviews                                      | Phenomenological  | Secondary care; UK               |
| Shawe JA. <i>The Prevention of Unplanned Pregnancy in Women with Type 1 or Type 2 Diabetes Mellitus: A Case Study: (Reproductive Choices and Preconception Care)</i> . PhD thesis. Guildford: University of Surrey; 2008 <sup>41</sup>          | To examine the issue of unplanned pregnancy in women with diabetes mellitus in order to understand what factors promote or discourage effective PCC | 107 women with pre-existing diabetes mellitus of mixed parity and 16 health-care professionals                  | Analysis of records; questionnaires; interviews | Thematic analysis using NVivo and SPSS                      | Secondary care; UK               |
| Spence M, Alderdice FA, Harper R, McCance DR, Holmes VA. An exploration of knowledge and attitudes related to pre-pregnancy care in women with diabetes. <i>Diabet Med</i> 2010; <b>27</b> :1385–91 <sup>42</sup>                               | To determine knowledge and attitudes of women with T1DM and T2DM of childbearing age towards pre-pregnancy care                                     | 24 white and Asian women of mixed parity with T1DM (n = 18) or T2DM (n = 6)                                     | Focus groups                                    | Content analysis  | Secondary care; UK               |
| <sup>a</sup> Woolley M, Jones C, Davies J, Rao U, Ewins D, Nair S, Joseph F. Type 1 diabetes and pregnancy: a phenomenological study of women's first experiences. <i>Practical Diabetes</i> 2015; <b>31</b> :13–18 <sup>43</sup>               | To explore women's perceptions and experiences of being pregnant and having T1DM in the transition to motherhood                                    | Seven nulliparous pregnant women with T1DM  | One-to-one interviews                           | Colaizzi method   | Secondary care; UK               |
| SPSS, Statistical Package for the Social Sciences. a Identified via manual search.  |   |   |   |   |                                  |

## Quality appraisal of included studies

Using criteria established by Walsh and Down,<sup>23</sup> AT and SE carried out the quality appraisal of the 18 selected sources. The results of this quality appraisal are given in *Table 3* in the form of a narrative summary of each study.

**TABLE 3** Quality appraisal of included studies

| Stages  | Narrative summary   |
|---|---|
| <b>Berg M, Sparud-Lundin C. Experiences of professional support during pregnancy and childbirth – a qualitative study of women with type 1 diabetes. Diabetic Med 2009;27:92–100<sup>26</sup></b> |   |
| Scope and purpose   | Previous studies about pregnant women at high risk were discussed. It was stated that ‘research on how women with diabetes perceive support received during pregnancy and childbirth is limited’. This led on to the aim of the study, which ‘was to explore the need for and experience of professional support during pregnancy and childbirth among women with type 1 diabetes’  |
| Design  | Six focus groups and four individual interviews were conducted with 23 women, 6–24 months after delivery. The study was conducted with a reflective, hermeneutic, lifeworld research approach, emphasising that understanding of human beings’ lifeworlds is necessary to grasp how they relate to and interact with the world. The settings, participants and data collection were described and a study group characteristics table was drawn   |
| Sampling strategy   | The sampling strategy was recruitment of primiparous and multiparous Swedish-speaking mothers with at least 6 months after delivery in the four hospitals’ delivery wards. The purpose was to obtain reports of varied experiences of received care and support. Twenty-five mothers agreed to participate in a focus group and six failed to take part for last-minute reasons. Further details were given   |
| Analysis  | Both researchers (CSL and MB) were present during the interviews; one was acting as moderator and the other taking field notes on the interactions and asking complementary questions. The interpretative analysis of all transcribed text was directed towards discovering varied qualitative meanings of the phenomenon ‘the need for and experience of professional support in relation to glycaemic control during pregnancy and childbirth among women with type 1 diabetes’. Further analysis identified eight themes of meaning, classified under pregnancy or childbirth, forming a basis for a final whole interpretation of the explored phenomenon. No predetermined hypotheses, theories or interpretive sources were used  |
| Interpretation  | The interpretation effects related to the focus groups were an additional layer of data, as combining focus group discussions and individual interviews was not a decision made at the start. Extensive use of quotations in the eight themes identified were used to show the interpretations that led to the conclusions  |
| Reflexivity   | The relationship between the two researchers and participants was discussed. No evidence of how complications were dealt with was reported  |
| Ethical dimensions  | The study was approved by the regional ethics board (number 351–07). A list of mothers was given to the first author, who contacted them with written and verbal information about the study. No further demonstration of sensitivity to ethics concerns has been described   |
| Relevance and transferability   | MB had extensive experience as a ‘diabetes midwife’ and CSL as a neonatal nurse, both at one of the four included hospitals in the study. However, the authors did not treat any of the included participants during the study period. They are aware that closeness to a study phenomenon may have an impact on the data but consider this to be an asset, rather than a problem, especially when applying a hermeneutical approach, which is based on the assumption that there can be no understanding without pre-understanding. Regarding the transferability of their findings, the participants represented a panorama of women with T1DM in the region; they came from both rural and urban areas and had been provided with a variation of antenatal care models, depending on which health-care institution they attended. Their educational level was fairly comparable with that of a normal population |
| Short narrative summary of the study quality  | Quality assessment: the authors used focus groups and interviews to achieve their aim. The 25 participants were recruited from four sites. The eight themes identified were supported with quotations and discussion, leading on to the conclusion of the difficulty in creating a model of care that suits everyone. Implications of quality assessment: as no predetermined hypotheses, theories or interpretive sources were used, the quality of data analysis is difficult to measure  |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary   |
|--|---|
| <b><i>Chuang CH, Velott DL, Weisman CS. Exploring knowledge and attitudes related to pregnancy and preconception health in women with chronic medical conditions. Matern Child Health J 2010;14:713–19<sup>27</sup></i></b>                                |   |
| Scope and purpose  | Little is known about whether or not women with chronic medical conditions understand their pregnancy-related risks, how these conditions influence intent for pregnancy and how chronic conditions influence pregnancy avoidance and/or pregnancy planning behaviours. The objective of this study was to explore pregnancy and preconception health knowledge and attitudes in the context of specific chronic maternal diseases (diabetes mellitus, hypertension and obesity). The reasoning behind choosing these specific medical conditions was also provided. There are clear reasons stated for the rationale of this study   |
| Design   | 12 focus groups were conducted with 72 participants. The breakdown of the focus groups was provided along with a table of the focus group guide   |
| Sampling strategy  | Sampling strategy was given. Women aged 18–45 years with diabetes mellitus, hypertension or obesity were recruited through advertisements (newspaper, radio, internet), flyers posted in community settings and clinical sites at the Penn State Hershey Medical Centre and from a volunteer research database of people with diabetes mellitus. Women who responded were screened by telephone for eligibility. Along with a statement of what the eligibility criteria consisted of was described   |
| Analysis   | Two members of the research team independently analysed each transcript, using a modified grounded theory approach to identify themes related to the topics discussed. Illustrative examples of the themes were selected. The NVivo 8 software package for qualitative data was used to categorise the responses into the appropriate themes. Four major themes were identified in the analysis: (1) knowledge about pregnancy risks related to chronic medical conditions was limited, (2) pregnancy intentions were affected by diabetes mellitus and hypertension, (3) knowledge about optimising preconception health was limited and (4) lack of control over avoiding pregnancies, including limited knowledge about how medical conditions might limit contraceptive choices. A table was produced to show the four themes identified for each medical condition |
| Interpretation   | The focus groups were conducted by trained facilitators. Groups were facilitated by a female moderator, who had extensive moderating experience and was not involved with the design of the study. A trained observer was also present as a note-taker. All sessions were audio-taped and video-taped; audiotapes were transcribed by a professional transcription service  |
| Reflexivity  | No discussion about the relationship between the researcher and the participants during the fieldwork was given. No evidence of how complications were dealt with was reported  |
| Ethical dimensions   | This study was approved by the Penn State University School of Medicine's Institutional Review Board (Hershey, PA, USA). Informed written consent was obtained before the focus group sessions and each woman was compensated for her participation   |
| Relevance and transferability  | The small sample size limited the generalisability of the study considering that three conditions were included. The sample was highly educated (93% had at least some college education), which means that even the limited knowledge levels observed with respect to pregnancy risk could be overestimated. There was no assessment of value/empowerment for participants. Further directions for investigation were stated   |
| Short narrative summary of the study quality   | Quality assessment: focus groups were conducted with 72 women, of whom only 16 had diabetes mellitus. The four major themes identified were supported with quotations and discussion. However, no conclusions were drawn. Implications of quality assessment: the paper explores women with chronic conditions having exposure to counselling about pregnancy-related risks and whether or not risk perception influences desire for future pregnancy. The quality of data analysis supports this exploration   |
| <b><i>Collier SA, Mulholland C, Williams J, Mersereau P, Turay K, Prue C. A qualitative study of perceived barriers to management of diabetes among women with a history of diabetes during pregnancy. J Womens Health 2011;20:1333–9<sup>28</sup></i></b> |   |
| Scope and purpose  | The importance of gestational diabetes mellitus is described in the introduction of the paper. Percentages of comparisons with progression to T2DM are also given. No aims were stated. To the authors' knowledge, data on women with pre-gestational diabetes mellitus were sparse and women's knowledge of the relationship between diabetes mellitus and birth defects has not been well researched. In this study, formative research was used to explore knowledge, attitudes and barriers to achieving and maintaining glycaemic control before, during, and after pregnancy among women with pre-gestational diabetes mellitus and gestational diabetes mellitus   |

continued

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages                                       | Narrative summary  |
|--|--|
| Design                                       | No rationale was given as to why focus groups were conducted. Six focus groups were conducted with women with pre-gestational diabetes mellitus and 10 groups with women with gestational diabetes mellitus, giving a total of 16 groups with 89 participants. A table presenting the breakdown of the focus groups (in terms of ethnicity) was provided   |
| Sampling strategy                            | The study aimed to obtain a random, representative sample of eligible low-income women from Atlanta. The sampling strategy was justified and a range of recruitment methods were used. Initial methods of recruitment included media advertisement, personalised mailings and the use of notices and flyers in community settings. Due to slow recruitment other methods were used including in-person recruitment within health settings. Disparities between the planned and actual sample were not explained  |
| Analysis                                     | All focus group sessions were tape-recorded and transcribed. Focus group transcripts were analysed by two coders. Detailed breakdown of how the coding was conducted has been described in the paper. Transcripts and observer notes were read by all members of the research team to develop a codebook containing an initial list of themes. Working independently, each coder then analysed all of the transcripts and additional codes generated were added to the codebook. Reliability statistics were generated for all transcripts and then transcripts were recoded and analysed accordingly. ATLAS.ti software (Scientific Software Development, Berlin, Germany) was used to assist with coding. The authors made a simple tally of unique participant mentions instead of the total number of mentions to limit the impact of the repetitions by individual participants. They then grouped the unique mentions into broader themes. Themes were sorted to determine if it was a frequently mentioned theme (major) or an occasionally mentioned theme (minor). The authors also examined themes to see if they were mentioned across all the women's groups or only specific segments. Finally, the authors made a network view to visually depict the themes that emerged from each question |
| Interpretation                               | How the analysis was conducted was presented in the paper. The analysis was done by two coders. The team spent time coding the data. Details of this were given in the 'focus group analysis and coding' section. There is extensive use of interview quotations in the results section of the paper   |
| Reflexivity                                  | There was evidence of insight as additional questions were designed to elucidate pregnancy planning behaviours and to explore what resources encourage participants' sense of self-efficacy in carrying out the intended behaviour (such as glycaemic control). Table 2 in the original report was presented showing example questions related to six different topics   |
| Ethical dimensions                           | No further detail about ethical dimensions was given. The final research protocol and all study materials were submitted to and approved by appropriate institutional review boards. All discussion groups began by reviewing a written summary of the relevant participant's information. No sensitive data were obtained from the participants, and only first names were used during the meeting. All information related to the project was stored in locked filing cabinets. Because of privacy concerns, they did not collect information about income for all participants. The socioeconomic background of the general population from which their convenience sample was drawn varied   |
| Relevance and transferability                | According to the authors, this was the first study to assess women's knowledge of the relationship between diabetes mellitus in pregnancy and birth defects and the first to compare women with pre-gestational diabetes mellitus and gestational diabetes mellitus. The results were supported by evidence. Literature was used to help support the findings of this paper. Other previous work was also referenced when 'participants described difficulty negotiating a disconnected health-care system, including trouble scheduling appointments with specialists and keeping each provider informed'. After this research, new education materials were developed. Giving new insights and increasing understanding for the women in these situations. Further directions for investigation were outlined, such as 'campaigns to improve awareness and knowledge about the benefits of pregnancy planning and preconception care'. There was no comment on whether or not the purpose of the research was achieved   |
| Short narrative summary of the study quality | Quality assessment: focus groups were conducted with black, white and Hispanic women. Five main areas of barriers to management of diabetes mellitus during pregnancy were identified. Pregnancy planning was not identified as a strategy to ensure a healthy baby. Implications of quality assessment: the paper presents quotations to support the claims made when needed and the discussion was supported by relevant literature. Changes were made and education materials were developed after the study was carried out  |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary  |
|--|--|
| <b>Devido J. Exploring the Role of the Parish Nurse in Providing Diabetes Education and Preconception Counseling to African American Women Using a Community-Engaged Mixed Methods Approach. PhD thesis. Pittsburgh, PA: University of Pittsburgh; 2014<sup>29</sup></b> |  |
| Scope and purpose  | The purpose of this study was clearly stated to explore the experiences of parish nurses in providing diabetes mellitus education and preconception counselling to women (especially African American women) with diabetes mellitus and their understanding of diabetes mellitus with regard to pregnancy and pregnancy outcomes, and to describe the parish nurses' knowledge and teaching self-efficacy regarding diabetes mellitus, pregnancy and PCC. The link between this research and existing knowledge was demonstrated. Papers were referenced that compare Caucasian and African American women's pregnancy facts during diabetes mellitus. The role of parish nurses with pregnant women with diabetes mellitus was also referenced with other work. The study was thoroughly contextualised by existing literature. The author included sections titled 'gaps in knowledge' and 'innovations and importance of proposed research' |
| Design   | A mixed-methods concurrent embedded design was used. Qualitative inquiry with focus groups was the primary method and quantitative inquiry was the secondary method. Rationale was provided for the use of such design. Triangulation of multiple data sources was used. The focus group methodology was chosen to gain a better understanding of the participant's lifeworlds. Participants were given incentives for taking part, including an online preconception counselling program. Data collection procedures were discussed in detail. A structured focus group guide was presented in the appendix   |
| Sampling strategy  | Participants were recruited from a database that contained an estimated 900 parish nurses. Alternative participation methods were offered to those located further away. Size limitation was also discussed by the author. The inclusion and exclusion criteria for study participation was clearly stated. Purposive sampling was used for recruitment to obtain broad representations. The participant response rate to recruitment was discussed. In the end, 11 focus groups were held with 48 participants. A table of 'total planned enrolment' with racial and ethnic breakdown of participants was presented   |
| Analysis   | Focus groups were conducted until data saturation was reached. Qualitative content analysis was conducted and combined with descriptive measure analysis. A total of 17 qualitative themes were identified from the focus groups and were listed. The reasoning behind the use of qualitative content analysis was given along with references. Data collection, coding and analysing occurred simultaneously. Other researchers independently coded the same transcripts. The study shows evidence that more than one researcher was involved in the stages and that this reduces bias. Data screening procedures were documented in detail. Statistical software (SPSS) was used for descriptive statistics  |
| Interpretation   | There was extensive use of quotations in the discussion of the findings and themes. There were data used to support the interpretation that led to the conclusions. Evidence was documented on the researcher taking time to be immersed in the data, reading through each transcript several times to look for patterns and meanings  |
| Reflexivity  | As this was a PhD thesis, a preface section described the relationship between the researcher and the research participants and how this research personally affected the researcher. The previous experiences and certifications of the researcher were also discussed. This showed the effects of the research on the researcher   |
| Ethical dimensions   | There was documentation of how autonomy, content, confidentiality and anonymity were managed. Data management was discussed in detail, including how all transcripts were stored and who could access them. Each participant was given a unique identification number for the focus groups. Participants were also assigned a unique identification number for the quantitative measures. A section titled 'research participant risks and protection' was included in the thesis  |
| Relevance and transferability  | The authors showed insight by stating the potential limitations to the study and what was the strategy used to address this limitation. The sample type was a limitation; hence why purposive sampling was used to minimise bias. Only one reference was used in the discussion of the results, which was a review paper. More references were needed from similar settings and studies, to draw comparisons, etc. There was a whole section on study strengths and limitations. Further directions for investigation have been outlined. This study has led to a community-engaged research project to develop a prototype for technology-based training program for parish nurses and a prototype e-health education resource for parish nurses to use. This study was significant for current policy and practice, especially regarding African American women. The purpose of the research was achieved                                    |

continued



**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary   |
|--|---|
| Short narrative summary of the study quality   | Quality assessment: the study was a PhD thesis and consisted of focus groups. There was great detail in all the appraisal stages, with the thesis being much longer than any paper. The appropriate method was used for the study. There were qualitative and quantitative aspects to the study. Implications of quality assessment: the purpose of the study was achieved. There was thorough detail and insight into the design of the study. This study resulted in further work that had an impact on current practice  |
| <b>Griffiths F, Lowe P, Boardman F, Ayre C, Gadsby R. <i>Becoming pregnant: exploring the perspectives of women living with diabetes</i>. Br J Gen Pract 2008;58:184–90<sup>30</sup></b> |   |
| Scope and purpose  | Clarity of focus was demonstrated referring to the outcome of CEMACH. Relevant studies have been stated and how this study differs to previous work done is also explained. The aim of the study is to explore women's accounts of their journeys to becoming pregnant while living with T1DM. A section of 'How this fits in' is also highlighted  |
| Design   | Semistructured interviews were conducted with 15 women living with pre-gestational T1DM, between 20 and 30 weeks' gestation and with a normal pregnancy ultrasound scan. The rationale for using qualitative design has been given. The setting (four specialist diabetes mellitus antenatal clinics) and participant recruitment was described   |
| Sampling strategy  | Only women who were able to be interviewed in English were included in the study. All women were white British, except one white European. Women were recruited via four specialist diabetes mellitus antenatal clinics in the West Midlands of the UK. The project researcher attended clinics when a woman with pre-gestational diabetes mellitus attended for the first time, introduced the study to each woman and arranged to contact interested women to schedule an interview. The clinic midwives assisted with recruitment when the researcher was unable to attend. During the 7 months of recruitment, 19 women were eligible to take part. One woman refused because of bereavement, two were hospitalised before the interview took place and contact was lost with one woman who initially consented                         |
| Analysis   | The whole research team participated in analysis of the interviews. Initially the team each read three transcripts (a total of nine transcripts between them) then discussed these. Further analysis proceeded in two ways. Each transcript was read as a whole by at least two team members and the women's accounts of their pregnancies were summarised. Thematic codes were identified from the interview schedule and from the team's reading of the transcripts. These thematic codes were reviewed and refined by two team members before the interviews were thematically coded using NVivo software. Further team discussion focused on comparisons between the summaries of each woman's pregnancy experience and comparisons between women theme by theme  |
| Interpretation   | The whole research team participated in analysis of the interviews. Initially, the team each read three transcripts (a total of nine transcripts between them) then discussed these. This indicates how the time was spent on dwelling with the data. Quotations have been used in the two themes exploring 'the journey to becoming pregnant' and 'advice from health-care professionals on living with diabetes mellitus and pregnancy'. Appendices 1–6 of the original report illustrated diversity with summaries of the experiences of five women including what they said about taking positive steps towards becoming pregnant, or not, and what they told us about action they took in relation to their diabetes mellitus, if any  |
| Reflexivity  | No discussion about the relationship between the researcher and the participants during the fieldwork was given. The midwife was used whenever the researcher could not make it. No evidence of how complications were dealt with was reported  |
| Ethical dimensions   | No mention of ethics approval was stated. However, it was mentioned that participants' names were changed to protect their identity   |
| Relevance and transferability  | The authors have provided a text box titled 'how this fits in'. 'The study highlights the importance of health professionals tailoring advice for women living with diabetes to each woman's current situation and suggests why formal pre-conception advice has limited impact'. How the findings of this study fit in with other studies is also mentioned in the discussion. There is also a section on 'strengths and limitations of the study', along with 'implications for clinical practice and future research'. The authors also outline further directions for investigation, 'further research is needed to assess the potential for unintended adverse effects of these sessions on women's psychological well-being. Further research is needed to understand the experience of women with type 2 diabetes becoming pregnant' |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary   |
|--|---|
| Short narrative summary of the study quality   | Quality assessment: the authors provide a good background as to why the study was conducted and how the study fits in with other work and literature. Quotations were provided when necessary to help support the discussion. Suggestions for further research were given. Implications of quality assessment: the authors explored women's account of their journey to becoming pregnant by their description of the 40 pregnancies. Appendices were used well to illustrate the diversity of the summaries of women's experiences   |
| <b>Holing EV, Beyer CS, Brown ZA, Connell FA. <i>Why don't women with diabetes plan their pregnancies?</i> Diabetes Care 1998;21:889–95<sup>31</sup></b> |   |
| Scope and purpose  | The objectives of the study were clearly stated 'to determine why women with diabetes mellitus generally do not plan their pregnancies'. The purpose of the study was to learn from women with diabetes mellitus what factors and circumstances promote or discourage effective pregnancy planning. The authors hoped to identify opportunities when health-care professionals might increase the level of timely pregnancy planning in women with diabetes mellitus. Previous studies on why women with diabetes mellitus do not plan their pregnancies were referenced  |
| Design   | Women with planned and unplanned pregnancies were compared using quantitative and qualitative analysis of self-administered questionnaires, medical record data and in-depth personal interviews. No rationale for the use of qualitative design was given. A population based sample of 85 women with diabetes mellitus diagnosed before the index pregnancy were recruited  |
| Sampling strategy  | Sampling was done after searching birth certificate data for 1987–91. A total of 15 hospitals agreed to take part. A staff member from each hospital monitored all births to women with diabetes mellitus and identified potential subjects. The inclusion criteria were English-speaking women, aged $\geq 16$ years, who had diabetes mellitus diagnosed before the onset of their most recent pregnancy. A total of 13 pregnancies were excluded from the study owing to adverse perinatal outcomes  |
| Analysis   | The paper gives details on how data analysis was conducted for both qualitative and quantitative data. 'The $\chi^2$ test or Fisher's exact test was used for between-group comparisons of categorical variables and Student's <i>t</i> -test was used for comparisons of continuous variables. For the two standardized scales . . . logistic regression was used to measure the impact of these variables on pregnancy planning'. For the interview data, content analysis was used to compare women with planned and unplanned pregnancies. The topic areas were listed as contraceptive behaviour, desire for motherhood, knowledge about the risk of birth defects, advice about pregnancy given by the health-care provider and relationship with provider  |
| Interpretation   | When developing the interview tool, questions were generated to examine in-depth eight themes (contraceptive use, pregnancy planning behaviour, desire for motherhood, partner relationships, health locus of control, knowledge about diabetes mellitus and pregnancy, medical advice received and relationships with health-care providers). Time was spent analysing the interview line by line, response categories were identified and defined and coding rules were developed to code subject responses into categories. The relationships and interactions within categories were examined across subjects and patterns of pregnancy planning behaviour were identified. The primary investigator coded each interview. Details of how the second researcher coded the interviews were also given. Inter-rater reliability was calculated. Discrepancies were discussed between the authors and the final coding was agreed between them |
| Reflexivity  | The relationship between researcher and how the recruitment was conducted was stated. No other information about fieldwork was given. Some insight was presented in the conclusions section of the paper 'it is likely that this subset would have had poorer glycaemic control peri-conceptually and, possibly, a greater proportion of unplanned pregnancies than those included in the study'  |
| Ethical dimensions   | The Washington State Human Subject Review Board asked that women be excluded if their infants experienced unfavourable perinatal outcomes (stillbirth, neonatal death, or birth defects that were life-threatening or required surgery). No other information regarding ethics committees was given   |
| Relevance and transferability  | The findings from this study differ from those done by others; this was discussed in the conclusions section. Suggestions on how to have maximal effect on pregnancy planning were given. Perhaps having the partner present in the pregnancy planning consultation would be one. Limitations of the study were discussed, therefore the actual rate of unplanned pregnancies in women with diabetes mellitus is likely to be even higher than that reported in the paper. The authors found an interconnected web of circumstances associated with poor pregnancy planning. The paper did not outline any further directions for investigation or how the research can be taken forward. The aims of the research were achieved  |

continued



**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages  | Narrative summary   |
|---|---|
| Short narrative summary of the study quality  | Quality assessment: the authors provide a good background with references about why it is important for women with diabetes mellitus to plan their pregnancies. There were three methods of data collection (qualitative and quantitative): personal interviews, self-administered questionnaires and medical records review. The paper focused more on the quantitative aspects of data presentation. No quotations were presented to support the conclusions. No suggestions for further research were given. However, ways in which pregnancy planning could be better delivered were discussed. Implications of quality assessment: the authors did achieve their purpose and provided suggestions on improving pregnancy planning counselling  |
| <b>King R, Wellard S. Juggling type 1 diabetes and pregnancy in rural Australia. <i>Midwifery</i> 2009;25:126–33<sup>32</sup></b> |   |
| Scope and purpose   | The objectives of the study were clearly demonstrated ‘to explore the experiences of women with T1DM, living in rural Australia, while preparing for pregnancy and childbirth’. In addition, the authors ‘aimed to describe the women’s engagement with, and expectations of, health-care providers during this period, and subsequently highlight potential service and informational gaps’. The lack of knowledge regarding international guidelines for the care of women with diabetes mellitus during pregnancy was discussed. The aspect of living in rural communities was also highlighted  |
| Design  | Rationale was given for the use of qualitative design in the study. This was because women were able ‘to provide personal and individual insights into the context of juggling diabetes mellitus self-care and their preparation for pregnancy and childbirth’. A ‘collective case study’ design was used to conduct the seven in-depth interviews. The setting was appropriately selected as being an Australian-wide study  |
| Sampling strategy   | Participants were recruited within 2 months. Sampling was by contacting women by placing notices at local diabetes mellitus services and via a website providing information to young people with diabetes mellitus. No disparity between planned and actual sample was explained. No response rate or drop-out rate was given. No justification for sampling strategy was given. The inclusion criteria were listed  |
| Analysis  | All interviews were audio-recorded and transcribed verbatim by a professional transcriber, the accuracy of transcripts was checked by the researcher. Thematic analysis was done by repeated reading of transcriptions and listening to tapes allowed categorising and grouping of themes. However, there was no discussion of how the coding systems evolved. Regularities and irregularities were identified and discussed by the team, stating that more than one researcher was involved in the stages  |
| Interpretation  | There were four themes reported, all with appropriate quotations to support the themes. No discussion of research processes was provided  |
| Reflexivity   | One researcher interviewed the seven women either face to face or by telephone, at a place and time convenient to them. No specific questions were asked; rather, a number of predetermined topics were included in a conversational style interview with each participant. Rapport was established through empathetic listening. During the interview, the interviewer verified participants’ responses by regularly reframing and feeding back the responses. No further information about the researcher’s relationship with the participant was given   |
| Ethical dimensions  | Ethics approval was obtained from the relevant university HREC. All potential participants were provided with a plain language information sheet explaining the study and what their participation would involve. Women were asked to sign a consent for their participation beforehand   |
| Relevance and transferability   | The seven women in the study resided in five separate states of Australia and, although this was a small qualitative study, the findings highlighted common themes related to the management of blood glucose levels, women’s informational needs and health service provision. The study was compared with others in literature and common themes were identified. The problem of women living in rural settings was also discussed, including government policy and funding limitations in such areas. Risks associated with women driving long distances to receive the appropriate care were also highlighted. Further suggestions for improvement of preconception counselling for women with diabetes mellitus were given. Further directions for investigation were also highlighted. The aims of the research were achieved in this study |
| Short narrative summary of the study quality  | Quality assessment: this qualitative study had a specific focus on rural Australia. The discussion suggested improvements for access to health care for these women with references to guidelines that are often neglected. The sampling strategy was weak and no background of the women who were interviewed was given. Implications of quality assessment: the authors did achieve their aim in exploring the experiences of these women; however, with no sampling strategy and no mention of data saturation, using such a small sample hinders the effectiveness of the study   |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary  |
|--|--|
| <b>Lavender T, Platt MJ, Tsekiri E, Casson I, Byrom S, Baker L, Walkinshaw S. Women's perceptions of being pregnant and having pregestational diabetes. <i>Midwifery</i> 2010;26:589–95<sup>33</sup></b> |  |
| Scope and purpose  | The objective of the study was 'to explore the experiences of white British and South-East Asian women with type 1 and type 2 diabetes, and the perceived impact of diabetes on their reproductive health'. This was clearly stated in the paper. The gap in literature was stated in the introduction; specific studies that have intended to fill this gap were referenced along with reasons why this study was needed. The study was thoroughly contextualised by existing literature  |
| Design   | A hermeneutic phenomenological approach was used to explore the perceptions of women with diabetes mellitus from two different cultural backgrounds with varied reproductive health experiences. Focus groups and one-to-one interviews were used to elicit 22 women's experiences. An interpretive analytical approach was conducted by two researchers. A choice of individual or focus group interviews was offered and these were arranged at mutually convenient times for the participants. Baseline data were collected on a brief questionnaire, prior to interview. Information sought included age, year diagnosed with diabetes mellitus, frequency of self-testing, diabetes mellitus management (i.e. diet, tablets, insulin), additional significant health problems, number of hospital admissions in the last 5 years and whether these were diabetes mellitus related or reproductive health related. Table 1 of the original report gives the participant profiles for those in the study. A semistructured interview schedule was used to enable exploration of the broad areas of interest, while encouraging respondent-led inquiry |
| Sampling Strategy  | A purposive sample of pregnant and non-pregnant women was obtained from those attending specialist diabetes mellitus clinics in two areas in north-west England. An explanation of why purposive sampling was appropriate when using a phenomenological approach was also given, 'due to the importance of selecting individuals who have knowledge of the phenomena concerned'. South-East Asian lay researchers were also used to help with recruitment of that population. For the second study area, non-pregnant women of childbearing age were recruited from a unit which offers a multidisciplinary outpatient diabetes mellitus service. The fact that these 'sites have a relatively low ethnic minority rate, and the population varies in terms of sociodemographic details' was also stated. The researchers had thought into their sampling strategy and what kind of participants they were likely to get. A total of 49 women were sent an invitation to participate and 22 women responded. Reasons as to why other women did not get involved was not stated in the paper  |
| Analysis   | The data were managed manually, that is, without the aid of any software package. Translations were carried out. Individual segments of texts were considered in relation to the overall interview and each sentence was assessed for the meaning of the phenomena. This was a cyclical process, the researchers moved back and forth between the whole text and segments of the text to gain some understanding of the phenomena being explored. Throughout the paper there is evidence of more than one researcher's involvement and where the whole team had an involvement. Three main themes were found to contribute to the lived experience of the participants: relinquishing personal control, pregnancy overshadowed by diabetes mellitus and haphazard PCC  |
| Interpretation   | To meet this objective, it was crucial to search for the commonality as well as diversity of participants' experiences. This involved immersion in the data by reading and rereading each interview in a search for emerging themes. Individual segments of texts were considered in relation to the overall interview and each sentence was assessed for the meaning of the phenomena. This shows that time was spent by the researchers in dwelling with the data. Initially, only two researchers carried out simultaneous analysis. Collaborative reflective discussions were then done with the whole research team to generate deeper insights and understandings. Given that members of the team worked within the field of study, this enabled them to share their views of the way the description did or did not resonate with their own experiences. Themes were then examined, articulated, reinterpreted and reformulated. There was extensive use of quotations to support each theme that was derived from the data   |
| Reflexivity  | Interviews conducted in Punjabi and Urdu were transcribed and translated by the lay researcher. Back-translation was also conducted, along with an explanation of what that consisted of. There was some demonstration of researchers influence on stages of research processes, that is, the use of lay researchers and why   |
| Ethical dimensions   | Ethics approval was received by the local research ethics committee. Pseudonyms were used to protect the identity of the participants. Although African women were not part of the original eligibility criteria, an information sheet was sent to one woman in error. Given that this study was exploratory and this woman was keen to participate, she was included in the study. This shows the researchers had fair dealing with all research participants   |

continued

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages  | Narrative summary   |
|---|---|
| Relevance and transferability   | Limitations of the study were discussed and the sample size was reported as being limiting. Groups were not homogeneous. The South-East Asian women, for example, represented a number of different cultures but were grouped together in the study. The strengths of the study were also discussed 'it offers an alternative perspective i.e. that of the women, which should make health professionals question their approach to supporting women with diabetes'. The study had applicability to the health needs of a multicultural society, aided by the use of lay researchers, which was also unique. The interpretation of the results was plausible. The authors outlined further directions for relevant research to be done in the area along with strategies that need to be developed to ensure safety is maintained. The objectives of the research were achieved   |
| Short narrative summary of the study quality  | Quality assessment: the authors used focus groups and one-to-one semistructured interviews to achieve their objectives. The 22 participants were predominantly of two different ethnicities. The analysis resulted in the identification of three themes; these were supported with quotations and discussion, leading onto the conclusions. Implications of quality assessment: the paper had a clear focus and touched territory that had been previously unexplored. The researchers used additional techniques to help get the most out of the participant pool   |
| <b>McCorry NK, Hughes C, Spence D, Holmes VA, Harper R. Pregnancy planning and diabetes: a qualitative exploration of women's attitudes toward preconception care. J Midwifery Womens Health 2012;57:396–402<sup>34</sup></b> |   |
| Scope and purpose   | The problem relating to pre-gestational diabetes mellitus is highlighted in the introduction, with use of appropriate referencing. International guidelines, the American Diabetes Association and previous studies are also discussed and referenced. In the UK, the CEMACH survey was also referenced. The authors have demonstrated the link between this research and existing knowledge very clearly. A knowledge gap exists: 'there is very little published research that addresses women's attitudes toward seeking preconception advice and, hence, no information that identifies the salient behavioural, normative, or control beliefs that might motivate women with diabetes to seek preconception advice'. The aim of this study was stated to be 'to address this gap by exploring attitudes toward pregnancy planning and preconception care seeking among women with diabetes'  |
| Design  | In-depth semistructured interviews were completed with 14 non-pregnant women with T1DM. The rationale for using semistructured interviews was provided: these 'are considered an appropriate approach to capture lived experience and have been used in previous research to investigate perspectives of pregnancy among women with diabetes'. An appropriate setting was used for participant recruitment and as well as for the actual interviews (either at the participant's home or in an informal setting within the university). Table 1 in the original report presented the participants' characteristics, which show some information that was collected by the authors. The study employed a phenomenological approach to knowledge acquisition, involving a detailed examination of the participant's experience, focusing on understanding the individual's personal perceptions of her experience, while acknowledging that the participant's perceptions are elicited through a dynamic, interactive process and were interpreted by researchers |
| Sampling strategy   | Participant selection was carried out by finding eligible women who attended the participating hospital within the South Eastern Health and Social Care Trust (and registered on its database). These women were sent written information about the study and asked to return a reply form to indicate their interest in participation. From an initial sample of 40 women who were contacted about research study participation, 20 returns were received and a final sample of 14 women provided written consent to be interviewed. No detailed explanation why some women who had sent a reply were not interviewed was provided   |
| Analysis  | Analysis was an iterative process involving the exploration of emerging data following each interview. Details on how the transcripts were analysed was provided. All interview transcripts were read and annotated independently by the first and second authors in order to generate a list of common first-order themes. Following this, both authors worked together to cluster the first-order themes, generating a new list of themes. Transcripts were reread against these themes and a list of relevant transcript extracts were compiled under each. The authors also mention how discrepancies were dealt with. 'Discrepancies were discussed in order to reach a consensus, and discussion resulted in minor changes to the list of themes'. Analysis of the interview data revealed four main themes: (1) the emotional complexity of childbearing decisions; (2) preferences for information related to pregnancy; (3) the importance of being known by your health professional; and (4) frustrations with the medical model of care             |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages  | Narrative summary   |
|---|---|
| Interpretation  | There was evidence of full immersion in the research data as 'other members of the research team were involved in this final process of checking that the analysis of the interview transcripts had resulted in a coherent and integrative shared account and understanding of the issues, but that nuances were still preserved in the written summary'. The paper acknowledged that the researchers 'have their own beliefs and understandings' when interpreting the data. Interview quotations were used to help discuss the four themes that were developed  |
| Reflexivity   | Insight was used to help develop the interview schedule. 'The interview schedule was developed following a review of the literature on pregnancy, preconception planning and seeking preconception care among women with diabetes, and discussion within the research team, to inform a list of potential discussion topics on the interview schedule'  |
| Ethical dimensions  | Ethics approval was obtained from the Queen's University Belfast Ethics Committee and the Office for Research Ethics Committees of Northern Ireland (07/NIR02/140). No other information regarding ethical dimensions was given   |
| Relevance and transferability   | Previous studies were discussed, and differences from this study were highlighted. Similarities between the data in this study and previous studies are also discussed. Plausible interpretations are given: 'it is important to remember that women's perceptions and expectations about preconception care are likely to be informed by their existing experiences of usual diabetes care and their relationships with their existing health care providers.' Directions for further research are given. Weaknesses of the study were discussed in the 'methodological reflections and further directions' section, stating that 'the data from these interviews were less meaningful'. No value of empowerment for participants was measured from taking part in this study. Cultural aspects regarding the sample population were also discussed  |
| Short narrative summary of the study quality  | Quality assessment: the authors used semistructured interviews to achieve their aim of exploring attitudes towards pregnancy planning. The 14 participants all had T1DM. The analysis resulted in four themes which were identified, these were supported with quotations and discussion, leading to the conclusions. Implications of quality assessment: the quality of data analysis is good; however, the discussions did not refer back to the methodology used for the study. There were further directions for this research stated   |
| <b>Mersereau P, Williams J, Collier SA, Mulholland C, Turay K, Prue C. Barriers to managing diabetes during pregnancy: the perceptions of health care practitioners. Birth 2011;38:142–9<sup>35</sup></b> |   |
| Scope and purpose   | The objectives of the study were clearly stated to be 'to investigate the concerns of health care practitioners who care for women with a history of diabetes during pregnancy and their perceptions of attitudes and barriers to achieving good glycaemic control'. The importance of good glucose control was highlighted, along with the possibilities of the additional adverse outcomes that may result in poor control. Multiple papers were referenced here. The high prevalence of diabetes mellitus in the population of women of childbearing age was discussed, and this led to a discussion of where this study fits in. The American Diabetes Association guidelines were also referenced  |
| Design  | Six focus groups, two of each practitioner type, were conducted with physicians, mid-level practitioners and certified diabetes mellitus educators. The eligibility criteria for the participants were stated. Participants received reimbursement for their time and travel costs  |
| Sampling Strategy   | A list of eligible individuals was purchased from a private firm. This study used a random selection process to invite eligible practitioners. From an initial pool of 1706 practitioners, a total of 53 participated in six groups. Table 1 in the original report showed the breakdown in numbers and profession of those invited, responded, eligible and participated. Practitioners came from a variety of practice environments, including public health clinics, private offices, hospital outpatient facilities and managed care organisations  |
| Analysis  | In this study the Health Belief Model was used to explore those factors that a practitioner encounters in an effort to influence a woman's knowledge and behaviour associated with diabetes mellitus before and during pregnancy. Details of how the coding and analysis was done are provided. Two coders read all transcripts, noted emerging themes and developed a list of codes specific to each question to form the preliminary coding dictionary. They independently coded the transcripts and added codes to the dictionary as needed. A software package was used for the analysis. Inter-rater reliability was > 70% between the two coders. Themes were sorted into frequently mentioned themes (major) and occasionally mentioned themes (minor). The themes were plotted in a network view for a visual representation of each line of questioning in relation to both the major and minor themes |
| continued   |   |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary  |
|--|--|
| Interpretation   | Sample questions were shown in table 3 of the original report. An experienced qualitative researcher moderated all groups. There was extensive use of quotations in the results section, which shows how the interpretation of what was said in the focus groups led to the conclusions and recommendations  |
| Reflexivity  | There was no discussion of the researcher and the participants' relationship during fieldwork. The study did not show any evidence of self-awareness or insight beforehand. The two coders' influence on the stages of analysis was described in detail  |
| Ethical dimensions   | The final research protocol and study materials were approved by appropriate institutional review boards. The paper demonstrated sensitivity to ethics concerns well. Relevant human subjects' issues were reviewed at the beginning of each focus group. As a waiver of documentation of informed consent was justified, signed consent forms were not collected from participants. Only first names were used during the meeting and no sensitive data were obtained from the participants. All participant information related to the project was kept secure   |
| Relevance and transferability  | Findings from previous research were referenced. The authors acknowledged that the study had several limitations. The focus group method of research cannot be used to draw conclusions with broad applicability; however, it can guide larger-scale research endeavours. Owing to the sample of practitioners, the findings might not reflect the opinions and experiences of practitioners from other settings and other countries. Ways of reducing adverse pregnancy outcomes were suggested, including the involvement of both practitioners and patients. The study provided resources in Spanish and English for the education of women. There were new insights as a result of this study. Further directions for investigation were outlined in the conclusion of the paper   |
| Short narrative summary of the study quality   | Quality assessment: the study consisted of six focus groups to meet the objectives. There was considerable mention of ethics concerns for the participants. Implications of quality assessment: the paper was clearly focused on what health-care practitioners think the barriers are to managing diabetes mellitus. No details on the theory used was given and no justification as to why this design was used over others  |
| <b><i>Mortagy I, Kielmann K, Baldeweg SE, Modder J, Pierce MB. Integrating preconception care for women with diabetes into primary care: a qualitative study. Br J Gen Pract 2010;60:815–21<sup>36</sup></i></b> |  |
| Scope and purpose  | The paper states the aims clearly as exploring 'the perspective of GPs and secondary care health professionals on the role of GPs in delivering preconception care to women with diabetes'. Multiple papers were referenced that look at the prevalence of diabetes mellitus (both T1DM and T2DM) in pregnant women. Specialist care services are being provided in primary care now as well as secondary care. Guidelines with recommendations were also mentioned, using NSF and NICE guidelines. These guidelines failed to recommend an optimal delivery strategy. The knowledge gap existed on what health professionals think about the division of care and their respective roles in delivering PCC to women with diabetes mellitus, which is where the aims of this study fit in. There is another section in the paper titled 'How this study fits in'; the authors have made sure the study is thoroughly contextualised by existing literature |
| Design   | This was a qualitative, cross-sectional study. The setting used was a London teaching hospital and GP practices in the hospital catchment area. Semistructured interviews were conducted with 22 women of different ethnic backgrounds who had T1DM or T2DM and who had attended the hospital. Semistructured interviews were also conducted with health professionals associated with the hospital's multidisciplinary diabetes mellitus PCC team ( $n = 7$ ) as well as a sample of GPs ( $n = 8$ ) serving the catchment area of the hospital and responsible for the hospital referrals of the women participating in the study. The setting of the London hospital was appropriately selected. The rationale behind the use of a qualitative design was also provided   |
| Sampling strategy  | A total of 13 out of the 18 GPs were purposively selected, from different practices, to ensure adequate representation of involvement in diabetes mellitus care. GPs were contacted via telephone and sent information on the study via e-mail and post. In the end eight GPs agreed to be interviewed. The reasons behind why the others did not participate was not stated   |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages  | Narrative summary   |
|---|---|
| Analysis  | Thematic analysis using the framework approach was carried out. This involved the following steps: (1) familiarisation with the data, (2) identifying a thematic framework, (3) indexing, (4) charting and (5) mapping and interpretation. A software program for supporting qualitative data analysis was used to code, organise and retrieve coded segments. Descriptive themes derived from the questions were identified, as well as more analytical themes that emerged from the interpretative process of data analysis. Analyst triangulation and responder validation were used to ensure rigour in data interpretation. Four main factors influencing the GP's role in PCC emerged from the interviews. These were case load and patient profile; ambiguity of GP roles and responsibilities; missed opportunities; and integration of care. Research participants had involvement in the analysis and where a responder validation meeting took place with the hospital team after initial data analysis. Those who could attend did so |
| Interpretation  | Interviews were carried out by two members of the research team. The interview topic guide was provided in this paper. Two of the researchers met regularly throughout the duration of the data collection and analysis period. A responder validation meeting took place with the hospital team after initial data analysis. Reasons why GP participants could not attend were also given. The paper demonstrates that time was spent interrogating the data, as two researchers met regularly throughout the duration of the data collection and analysis period. Each researcher reviewed transcripts individually to identify data segments that related to the key objectives of the study as well as to identify emergent analytical themes. There was extensive use of quotations for the presentation of the four main results  |
| Reflexivity   | There was no discussion of the relationship between the researcher and the participant during fieldwork. The study did not show any evidence of self-awareness or insight beforehand. The two researchers influence on the stages of analysis were described. However, when there were discrepancies and how they were managed was not described  |
| Ethical dimensions  | Ethics approval was obtained from the Joint UCL/UCLH Committees on the Ethics of Human Research Committee Alpha. R&D approval was obtained from the Joint UCLH/UCL Biomedical Research (R&D) Unit and from North Central London Research Consortium. No other ethical dimensions were discussed. No evidence of fair dealing with all research participants and nothing was included on how autonomy, consent, confidentiality and anonymity were managed   |
| Relevance and transferability   | Strengths and limitations of the study were discussed. This was the only study in the UK to look at the perspectives of GPs and secondary care health professionals. However, the study was based on one case study and may not be representative of other areas. Further directions for investigation were outlined into perspectives of health professionals such as primary care nurses, family planning practitioners, community-based midwives and junior doctors involved in delivering general diabetes mellitus care. Findings from previous research were referenced and compared with this study. Suggestions on how the clinic should be run were also discussed, including software improvements. The authors achieved what they had set out to achieve   |
| Short narrative summary of the study quality  | Quality assessment: the study consisted of interviews from a larger study; however, the focus of this publication was the data regarding staff views and there was no real mention of ethics concerns for the participants. The study was unique and had its own agenda. Implications of quality assessment: the paper had a clear focus on expressing the views on staff who deliver the care. However, this was a one site case study   |
| <b>Murphy HR, Temple RC, Ball VE, Roland JM, Steel S, Zill-E-Huma R, et al. <i>Personal experiences of women with diabetes who do not attend pre-pregnancy care. Diabet Med</i> 2010;27:92–100<sup>37</sup></b> |   |
| Scope and purpose   | The aims of the study were clearly demonstrated: 'to explore the views of women who did not attend pre-pregnancy care, in particular their accounts of contraception, previous pregnancies and the influence of healthcare advice'. There is mention of the St Vincent declaration, NSF, CEMACH reports and NICE guidelines to highlight the importance of preconception counselling for women with diabetes mellitus. This puts the aims of the study in context. Some literature was referenced on the use of interviews for data collection  |
| Design  | Semistructured interviews were carried out with 29 pregnant women (21 with T1DM and eight with T2DM) at three UK specialist diabetes antenatal clinics. The reasoning behind the selection of interviews was also stated: 'interviews are particularly informative for exploring issues from the person's perspective rather than that of the health professional'. There was also reference to when interviews have been used for similar studies. This study participants were white and Asian/Pakistani women  |

continued



**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary   |
|--|---|
| Sampling strategy  | Researchers identified eligible women with the assistance of the clinic midwives and contacted interested women to arrange a semistructured interview during subsequent clinic visits. Table 1 of the original report gives the demographic and biomedical characteristics of the study participants. Thought had gone into extracting this information. A total of 29 women were interviewed; one woman declined to participate and her reason was also documented. The actual sample size would have been 30 women  |
| Analysis   | Detailed information on how the analysis and coding was constructed was provided. The interview transcripts were reviewed, refined and thematically coded using a framework approach. The main stages of this approach included reading and rereading interview transcripts to ensure familiarisation with the data and repeated listening to the original audiotapes. Who did what was also documented, the transcript from each interview was read by four researchers (including a lay team member). The use of a lay team member makes this study unique. One author developed an initial coding frame for content that related to the core focus of the study. This coding frame was then independently applied to the transcripts by three other researchers. Codes were accepted when two or more raters agreed. Differences were also dealt with when the three raters disagreed, one author reviewed the codes and allocated a code. The total number of codes for the data were also stated, along with the percentage of time researchers agreed |
| Interpretation   | The authors had thought about what kind of information they would want to extract: 'biomedical and clinical information was retrospectively obtained from the East Anglia regional diabetes mellitus pregnancy database'. There was a female translator present for one interview, and that interview was translated from Punjabi to English. Quotations were used in the discussion of the findings  |
| Reflexivity  | Training on conducting the interviews was provided by a health psychologist and the interview process was reviewed by the research team after the first six interviews. Examples of the open-ended questions were also stated in the paper. There was evidence of insight as the sample pool was selected to include women who had previous miscarriages or adverse outcomes. There was evidence on how problems with coding were dealt with between the authors  |
| Ethical dimensions   | To avoid potential bias, no interviews were conducted after a suspected poor pregnancy outcome or if a potential fetal abnormality was detected on the 20-week morphology ultrasound. This would also have been an ethical consideration. Anonymised data from all pregnancies affected by pre-gestational diabetes mellitus were obtained prospectively since 1999. Ethics approval for conducting the interviews and linking the interviewee to her biomedical and pregnancy outcome data were also obtained. All study participants gave written informed consent. The authors tried to avoid potential interviewer bias related to knowledge of the previous/current pregnancy outcomes, by having the biomedical and regional database records examined retrospectively  |
| Relevance and transferability  | Papers were referenced linking this study to those previously conducted. The US PRAMS reports were also referenced in the discussion of the paper. The significance of current policy and practice was outlined in the introduction and in the discussion. There were some differences between the white and Asian women in the study. Recommendations for clinical care were provided, 'health professionals must focus on engaging women in realistic discussions regarding reliable contraceptive behaviours, to find acceptable methods that women can sustain'. No further directions for investigation were outlined; instead the conclusions focused on how health-care professionals can approach the women better after they know they are on diabetes mellitus medications. No limitations of the study were discussed  |
| Short narrative summary of the study quality   | Quality assessment: the authors used interviews to find out experiences of women who do not attend clinic. There were useful tables provided with additional information on the participants or on participant quotations. Implications of quality assessment: the quality of data analysis is good; however, the discussions did not refer back to the methodology used for the study. There were no further directions for this research stated; the focus was on how health-care professionals can improve their care when they have such patients   |
| <b><i>O'Higgins S, McGuire BE, Mustafa E, Dunne F. Barriers and facilitators to attending pre-pregnancy care services: the ATLANTIC-DIP experience. Diabet Med 2014;31:366-74<sup>38</sup></i></b> |   |
| Scope and purpose  | The aim of this study was 'to better understand why women with diabetes mellitus (Type 1 and Type 2) choose to attend prepregnancy care services and to identify perceived barriers to attendance'. Facts about the complications of diabetes mellitus and pregnancy were given in the introduction of the paper. This study is part of a large research programme (ATLANTIC-DIP) that initiated a formal regional protocol-driven prepregnancy care programme. Other similar studies in Britain were referenced, leading onto the focus of this study's aims   |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages                                       | Narrative summary   |
|--|---|
| Design                                       | A participative health research method called the participative research process was used to facilitate 14 women with diabetes mellitus to create 'webs of ideas' on the reasons for attendance and non-attendance at a prepregnancy care programme and potential solutions for each obstacle. A description of what participative health research is was provided along with reasons why this was adopted for this specific study. Participant details were given in table 1 of the original report. These details were extracted with insight into what the study aims to represent   |
| Sampling strategy                            | Multiple avenues for advertising the study were adopted. Initially a list of women with T1DM or T2DM diabetes was compiled from data sets already established in primary and secondary care. A letter was sent to all GPs advising them of the service and inviting them to refer women as appropriate. Information evenings for professionals were convened in the region and information about the service was disseminated via newspapers and radio. In addition, an invitation letter was sent to each woman offering an appointment for a prepregnancy care clinic, followed by a telephone call 1 week later  |
| Analysis                                     | The participative research process facilitated participants as generators, analysts and presenters of their data, while retaining necessary degrees of methodological rigour to be both valid and reliable. The participants created seven 'webs of ideas' on factors influencing women's decision whether or not to engage with the prepregnancy care programme and how to address those factors in order to increase attendance. There were seven central factors selected by participants  |
| Interpretation                               | Participants were given coloured paper to write down their thoughts. Working in pairs, participants selected a theme around which they built a 'web of ideas'. Quotations were used to discuss the results for each of the seven central factors. The age and duration of time diagnosed with diabetes for the women in the group was similar to that previously recorded in the ATLANTIC-DIP population, the references to this were provided but no explanation was given in this paper. In terms of participants' ethnicity, the region has a mixed urban/rural population spread over a large geographical area, relatively homogeneous in terms of ethnicity   |
| Reflexivity                                  | The relationship between the researcher and participants was described. The participative research process was conducted as workshops facilitated by the first author, who was an expert in participatory health research, independent of the clinical service and the prepregnancy care programme and unknown to the women prior to their initial meeting. The authors thought this was considered important in facilitating the women to speak freely. There was no demonstration given of the researchers' influence on the stages of the research process. There was also no evidence on how complications were dealt with  |
| Ethical dimensions                           | Ethics approval was granted, this study being one component of a larger research project (ATLANTIC-DIP). No other information regarding the ethical dimensions was given  |
| Relevance and transferability                | With reference to other work, possible reasons were given as to why participants were not engaging with prepregnancy services. The webs also generated novel ideas on how to increase attendance that can inform health professionals as they try to determine how best to encourage women's attendance at prepregnancy care. The American Diabetes Association consensus guidelines on management of diabetes mellitus in pregnancy were referenced. The limitations of the study were discussed as having a small sample because of it being an exploratory addendum to a much larger project. In addition, the majority of women had T1DM; therefore, the outcomes of this study apply particularly to women with T1DM. A strength of this study was giving attention to the ethnic minority groups. Suggestions were made on how to improve care, the need for changes in the way the prepregnancy care service is delivered and the importance of social media in encouraging attendance and promoting the benefits of prepregnancy care. Further directions for investigation included the suggestion of the development of an app that would make available key knowledge points to all women, while providing contact details of services available |
| Short narrative summary of the study quality | Quality assessment: participative research process was used to facilitate 14 women to create a 'web of ideas'. Different methodology was applied, with results that have been found in other studies. As this was part of a large study, certain information was missing. Implications of quality assessment: the paper presents quotations to support the claims made when needed and the discussion was supported by relevant literature. Further suggestions on how the services can be improved were provided; however, they were very subjective   |

continued



**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary  |
|--|--|
| <b><i>Power ML, Wilson EK, Hogan SO, Loft JD, Williams JL, Mersereau PW, Schulkin J. Patterns of preconception, prenatal and postnatal care for diabetic women by obstetrician-gynecologists. J Reprod Med 2013;58:7–14<sup>39</sup></i></b> |  |
| Scope and purpose  | The objectives were clearly stated as 'to assess barriers to and quality of care received by pregnant women with diabetes from obstetrician-gynaecologists'. References were made to show how diabetes mellitus affects pregnant women, with possible reasons as to why this may be. Previous studies that indicate significant variation in care given to pregnant women with diabetes mellitus were also referenced  |
| Design   | This was a national survey that examined reported practice patterns of obstetricians regarding management of diabetes mellitus. The American College of Obstetricians and Gynaecologists research department mailed questionnaires to 1000 random members. There were five mailings, each one sent only to physicians who had not responded. Participants were not compensated for taking part in the study. There was no justification given for the use of questionnaires and whether or not it was the most appropriate method for the aim of the study. The setting as members of the American College of Obstetricians and Gynaecologists was appropriately selected. The data collection strategy was thought through as table 1 of the original report presented the practice setting and patient demographics  |
| Sampling strategy  | Initially 1000 representative practising fellows of the American College of Obstetricians and Gynaecologists were mailed a questionnaire. A total of 510 responded, resulting in a 55.1% response rate. No difference was found in the rate between men and women; however, non-respondents were found to be younger than respondents. There was no justification of sampling strategy given; however, the 1000 people mailed were randomly selected. The disparity between planned and actual sample was explained  |
| Analysis   | Cluster analysis was used on physician reports of their patient's characteristics to develop a dichotomy of practices. Reasons why some practices were not included were given. Statistical comparisons were made across the three groups in the study. Continuous variables as mean $\pm$ standard error of the mean, were reported. Frequencies were in percentages. <i>F</i> -tests were used for differences between the means, a Mann-Whitney <i>U</i> -test was used for scaled responses to test for differences between two groups and a Kruskal-Wallis test was used for differences among three groups. No qualitative analytical approach was discussed. Data were managed by software package as responses on the questionnaire were entered into the software package (SPSS) data file for analysis. No mention of researchers regarding the analysis was discussed. There was also no involvement of research participants in the analysis. There was no mention of data saturation either |
| Interpretation   | Results were presented in sections titled 'preconception care', 'prenatal care', 'concerns of physicians caring for pregnant women with diabetes', 'postpartum care' and 'potential barriers to treatment'. No quotations were presented in the discussion of the finding. All results were shown quantitatively. However, data were used to support the interpretation. No clear audit trail was provided. One author had the primary responsibility for data analysis and writing the manuscript   |
| Reflexivity  | There was no discussion of the researcher and the participants during fieldwork. The questionnaire was mailed out to them. They had no personal contact. The study did not show any evidence of self-awareness or insight beforehand. There was no discussion of how the questionnaire was developed. However, this was not explained in the paper   |
| Ethical dimensions   | The study was approved by the Institutional review board of RTI International. No other ethical dimensions were discussed in the paper. Nor was there any demonstration of sensitivity to ethical concerns   |
| Relevance and transferability  | References were given to other studies that found similar results as evidence that this study is in context. Suggestions for where practice could be improved were stated after discussion of the findings. Limitations of the study were discussed: all the physicians here were members of the same voluntary research network and the data were self-report. To increase understanding, educational resources were suggested for patients to help the physician increase awareness and knowledge of diabetes mellitus among women with or at risk of diabetes mellitus and of the strategies and practices to manage and ameliorate the harmful consequences. The significance that these results have on current practice was outlined. Further directions for investigation were not made. There was no comment on whether or not the objectives of the study were achieved   |
| Short narrative summary of the study quality   | Quality assessment: the study was of a questionnaire sent to a large number of randomly selected members of a research network. There was no real mention of ethics concerns for the participants. All data were presented quantitatively, with references to other studies to help support the findings. Implications of quality assessment: the objectives of the study were met. However, it was not a qualitative study  |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages  | Narrative summary  |
|---|--|
| <b><i>Richmond J. Coping with diabetes through pregnancy. Br J Midwifery 2009;17:84–91<sup>40</sup></i></b> |  |
| Scope and purpose   | The paper references multiple studies that have shown increased risk of poor outcome of pregnancy in women with diabetes mellitus vs. women without. In the UK, there could be a lack of preconception clinics available to women, which could be why there uptake is lower. There were many aims of the study, which were introduced after the concept of identity was explained, using references and theories. The aim of the study was to illuminate the richness of individual experience   |
| Design  | This prospective study used a phenomenological approach to explore how identity was linked to the improvement, and deterioration, of blood glucose control in 11 women with T1DM. As the essence of this research was to discover the patients' own interpretation of their experiences, a phenomenological approach was chosen as it helps researchers to understand subjective experience of the lifeworld. In keeping with this concept, this research had largely followed Husserl's philosophy. Husserl's philosophy was also explained in the paper. Interviews were conducted using an interview schedule by a single researcher during the first and third trimester of pregnancy and again approximately 6–12 months after the birth of their babies; when this could not happen this was stated                        |
| Sampling strategy   | Purposive sampling was used and the sampling size was kept deliberately small. All of the women with T1DM attending the joint obstetric/diabetic clinic in a district general hospital between October 2001 and April 2004 were invited to participate in the study. The exclusion criteria were listed. A total of 14 women were approached, 11 of whom agreed to participate in the study. Two individuals refused to take part in the study and reason for refusal was explained in the paper. Reasons why some participants could not give the second interview were also explained in detail  |
| Analysis  | Analysis started on a very small part of the data, which generated sets of categories, and the emerging hypothesis was tested by the steadily expanding body of data. Data were managed by hand with the reasoning behind that choice. Multiple copies were made of the transcripts, which were manually cut and pasted into the emerging categories. Although laborious, this method had the advantage of greater familiarity with the data than using a computer software package for analysis. All data were analysed using comprehensive data treatment, including deviant cases in the context of the constant comparative method   |
| Interpretation  | All of the women were Caucasian apart from one who was of Afro-Caribbean descent. This was a reflection of the background population where the study was conducted, which has a small ethnic minority population. Where the interviews were conducted was also stated in the paper. Field notes were taken before and during the interviews. The timings of the interviews were mentioned and how they were recorded (tape-recorded); they were then transcribed word for word as soon as possible after the interviews had taken place. The transcribing of the interviews included observations made at the time of the interviews. These data included voice intonation, pauses, non-verbal behaviour and the researcher's own feelings at the time. Reference to theorists who wrote about reliability and validity are made |
| Reflexivity   | There was no discussion of the relationship between the researcher and the participants during the fieldwork. As one researcher did the analysis, there was only that researcher's influence on the stages of the research process. No other authors were involved in the study. Therefore, there were no complications or disagreements with the analysis of the data   |
| Ethical dimensions  | There was no mention of ethics approval in the whole paper. In addition, there was no mention of how autonomy, consent, confidentiality or anonymity were managed. The participants were given a letter instead of a name  |
| Relevance and transferability   | Limitations of the study were mentioned, which included only one researcher for the collection and analysis of the data. However, verbatim quotations had been included to enable readers to judge for themselves whether or not the interpretation is a valid one. It was stated in the conclusions that 'practice has changed in the light of these findings', which shows great impact of the study. Other changes that have resulted since this study were also listed. This has been a great support to the pregnant women as the postnatal group are able to offer advice and reassurance. A comment on the aims of the research was achieved  |
| Short narrative summary of the study quality  | Quality assessment: the author used one-to-one interviews to achieve the aims of the study. The 11 participants were predominantly of white ethnicity. There was no mention of the ethics considerations. Implications of quality assessment: the paper had a clear focus to discuss how these women cope with diabetes mellitus during their pregnancy. The researcher showed insight on different theories used to comply with the reliability and validity of the study. The impact of the work was already measured when the paper was published   |

continued

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages  | Narrative summary  |
|---|--|
| <b>Shawe JA. The Prevention of Unplanned Pregnancy in Women with Type 1 or Type 2 Diabetes Mellitus: A Case Study: (Reproductive Choices and Preconception Care). PhD thesis. Guilford: University of Surrey; 2008<sup>41</sup></b> |  |
| Scope and purpose   | The study was introduced before leading on to the research problem and where this work fits in and the purpose of conducting this research. References were made to WHO, CEMACH and NSF, stating that there is little research in this area. The thesis aims to examine the issue of unplanned pregnancy in women with diabetes mellitus and to understand which factors promote or discourage effective PCC. The link between research and existing knowledge was demonstrated well. Literature was reviewed, the search parameters were stated. A thorough literature review was conducted and many relevant references were cited   |
| Design  | The study was based on an ethnographical approach. Reasons behind this choice were given. The feminist focus was also explained. An extended case method was used. The study used mixed methods with three sequential phases; a database study reviewed the GP records of 1683 women with diabetes mellitus and a comparison group. Questionnaires were returned from 107 women and 32 semistructured interviews. The setting chosen was appropriate for the study. A description of the four diabetes mellitus centres was also given. The centres were not named but were in the south of England. The data collection strategy was apparent and appropriate. Demographic information of the participants was collected along with information on medical history and contraception methods used by the women. These data were collected to capture the complexity of experience and illuminate context in sufficient detail   |
| Sampling strategy   | Non-probability purposive sampling was used to provide a clear focus for in-depth investigation. All health professionals who were contacted agreed to take part in the interview. The sampling strategy was discussed. A sampling frame for the women with diabetes mellitus was developed. A figure was provided showing the algorithm for sampling frame. It was the author's intention to select four types of women from each of the four sites for interview. A table of this breakdown of characteristics was also provided. This shows the author has intended to have a thickness of description to be achieved from sampling. No disparity between planned and actual sample was explained or justified. Women were given a choice of where to be interviewed  |
| Analysis  | SPSS was used for the database study review and for the questionnaires. NVivo was used to analyse the questionnaires. The preference of this method was explained. Authenticity and rigour were explained. Using mixed methods, the study may have increased validity by comparing results by triangulation of the data. The transcripts were transcribed either by the researcher or by the secretary and thoroughly checked multiple times. The data, after being imported into NVivo, were analysed by reading the narrative and assigning labels based on the meaning elicited from the narrative. Main categories for health professionals and main themes for women with diabetes mellitus were presented as figures. There was mention of author involvement only in the analysis stages. There was no mention of data saturation   |
| Interpretation  | Senior staff from diabetes mellitus centres were visited and they were enrolled into the study. The relationship was built between the researcher and the staff. Written information sheets were given to staff members and dates were arranged to come to diabetes mellitus clinics to hand out questionnaires to appropriate women. Field notes relating to clinic routines, environment and waiting times were made by the researcher in the diabetes mellitus clinics. After the interviews, further post debriefing notes were made by the researcher about their impressions of the overall process, anecdotes and any other relevant issues. A reference was provided to say that field notes are a running commentary and can start the process of data analysis during data collection. Field notes were also made during transcribing, of use of language, inflection and emphasis during the interviews; they were added to give context to the transcription |
| Reflexivity   | There was evidence of insight, as many sources of bias were listed including the researcher, the environment and methods of data collection. There was no mention of the relationship between the researcher and the participants during fieldwork. The researcher had the only influence on all stages of the research process. As this was a PhD thesis and took 5 years to complete; in the acknowledgements the author did state that her life has changed in many ways. Details of the effects of this research on the researcher were not provided. As there was primarily one researcher in this study, no evidence of how problems/complications met were dealt with was provided  |
| Ethical dimensions  | A number of ethical principles were followed, including: 'The right not to be harmed', 'The right of full disclosure', 'the right of self-determination' and 'the right of privacy, anonymity and confidentiality'. These were referred to with detail as to how this study adhered to these principles. All the necessary ethics approvals needed for the study were listed. What change the ethics committee requested was also discussed. To promote anonymity, the health professionals were not identified by profession within the study findings but were referred to as health professionals   |

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages   | Narrative summary  |
|--|--|
| Relevance and transferability  | <i>Chapters 2–11</i> of the original report all ended with a conclusion. There was discussion throughout on how this work related to other relevant literature drawn from similar settings and studies. In the final conclusion, references to national policy were made. The study identified areas for further research and exploration. This study was significant for current policy and practice as the author questions the evidence for prescribing 5 mg of folic acid to women with diabetes mellitus and also the current medicalised model of promotion of PCC, which is having little influence on women. The author proposed a tripartite model of care, using evidence found from this study. A whole chapter was provided on the emerging policy and research that has been published since this PhD was conducted. This shows the further significance that this work has on current policy and practice. The aims of this research were achieved and the author answered the six research questions separately and in great detail                                       |
| Short narrative summary of the study quality   | Quality assessment: the study was a PhD thesis and consisted of three phases. There was great detail in all the appraisal stages, with the thesis being much longer than any paper. The appropriate method was used for the study. Implications of quality assessment: the purpose of the study was achieved; six research questions were addressed in detail  |
| <b>Spence M, Alderdice FA, Harper R, McCance DR, Holmes VA. An exploration of knowledge and attitudes related to pre-pregnancy care in women with diabetes. <i>Diabet Med</i> 2010;27:1385–91<sup>42</sup></b> |  |
| Scope and purpose  | The aims of the study are clearly stated 'to determine knowledge and attitudes of women with type 1 and type 2 diabetes of childbearing age towards pre-pregnancy care'. Use of literature and appropriate referencing of similar studies leads the authors on to their aims for the study   |
| Design   | A total of 24 women (18 with T1DM and six with T2DM) took part in one of four focus group sessions. The focus group breakdown was clearly stated. However, there was no rationale provided on the use of focus groups over other methods of data collection. The focus groups sessions lasted between 30 and 65 minutes. The participants were compensated £20 for their time and travel cost. A topic guide was developed to explore the knowledge and attitudes of the participants, reflecting the NICE care recommendations. The settings of two hospitals was appropriately selected. Demographic data were collected using a questionnaire prior to the focus group  |
| Sampling strategy  | Potentially eligible participants, identified from outpatient records at two NHS hospitals, were mailed a study invitation letter from their consultant physician. Women interested in taking part then contacted the research team directly. The details of the responses were also stated in the paper. A total of 400 patients were invited to take part, of whom 90 (23%) contacted the research team to receive further information. A total of 40 women were enrolled, of whom nine withdrew on the day (the authors provided the reasons for their withdrawal) and a further seven did not attend their focus group (no reason stated)  |
| Analysis   | Focus groups were professionally transcribed verbatim and analysed by hand. The justification of this was not provided. Data analysis was undertaken using a conventional content analysis approach. The breakdown of the work done was stated in the paper: initially, two authors read and reread each transcript, highlighting segments of data that were coded by identifying persistent words, phrases, themes or concepts. Data were then grouped according to topic, allowing further identification of subgroups. Following coding, the data were categorised to reflect the overall sense of the data and the relationships between categories. Related categories were then grouped into themes. This was then followed by a discussion and comparison of the themes to verify accuracy of interpretation. Who this discussion was between was not stated; nor was there any evidence of how disagreements were dealt with. Investigator reflexivity, verification of data and codes and thinking theoretically were strategies used to ensure rigour in this analysis process |
| Interpretation   | Qualitative analysis identified five main themes: knowledge, quality of relationships with health-care professionals, organisation of care, the impact of beliefs and attitudes on advice giving, and women's attitudes to pre-pregnancy care advice. Although the themes are presented separately, they are interrelated  |
| Reflexivity  | There was no discussion of the researcher and the participants during fieldwork. The study did not show any evidence of self-awareness or insight beforehand. However, the collection of the demographic data shows that the researchers wanted to put certain information about the participants in context with the focus group discussions, although this was not linked in this paper  |
| Ethical dimensions   | The protocol was approved by the Office for Research Ethics Committees in Northern Ireland (08/NIR02/50). Participants were introduced on a first name basis at the focus groups and gave informed consent prior to filling out a short demographic questionnaire (the summary of these demographic details is provided in table 1 of the original report)   |

continued

**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages  | Narrative summary   |
|---|---|
| Relevance and transferability   | The authors stated that the strength of this work was that it 'included women of varying age and parity, with both type 1 and type 2 diabetes mellitus; representative of the women in need of diabetes mellitus pre-pregnancy care advice'. Barriers to why women do not seek pre-pregnancy advice were discussed. Ongoing changes to the way education had improved was also discussed (CD-ROMs and DVDs), so was the concept of peer support. Directions for further research related to this study were outlined. A limitation of the study was thought to be respondent bias and ethnicity. Other qualitative studies were also referenced and their limitations were the same as this study. A slight significance for change in current practice was hinted at. There was a concluding comment on the purpose of the research highlights   |
| Short narrative summary of the study quality  | Quality assessment: the author used four focus groups to achieve the aims of the study. The 24 participants were either white or Asian. Separation of who was put in which focus group was clearly stated. No rationale for the use of focus groups was given. Implications of quality assessment: the paper had a clear focus. There was no measurement of participant empowerment. However, further work in the right direction was suggested   |
| <b>Woolley M, Jones C, Davies J, Rao U, Ewins D, Nair S, Joseph F. Type 1 diabetes and pregnancy: a phenomenological study of women's first experiences. <i>Practical Diabetes</i> 2015;31:13–18<sup>43</sup></b> |   |
| Scope and purpose   | The aims of this study were to explore women's perceptions and experiences of being pregnant and having pre-existing T1DM, and to assess their physical, social, psychological, emotional and educational needs during their transition to motherhood. The introduction of the paper sets the scene on the facts about diabetes mellitus and pregnancy along with the multidisciplinary team's involvement in the care of the woman. Reference to the NICE guidelines and the NSF are also made. Other similar studies on the transition to motherhood are also referenced. Leading onto the aims of this study, which look at whether or not pregnant women in UK with pre-existing T1DM have similar experiences during their transition to motherhood  |
| Design  | The qualitative design incorporated a purposive sample of seven women in their first pregnancy. A series of open-ended questions were utilised during the first interview, which was described in detail in the paper. There was no rationale provided for the use of qualitative design and this methodology   |
| Sampling strategy   | A purposive sample of seven women were recruited to the study. The eligibility criteria were listed in the paper. Facts about the clinic were also stated, putting the setting of study in context with the sampling selection. Eligible participants were selected and approached initially by members of the diabetes mellitus team or by the diabetes mellitus specialist midwife. Women who showed an interest in taking part in the study were given a participant information sheet and asked if they were interested in becoming involved on their subsequent clinic visit. Those who agreed were contacted directly by the researcher. The number of women who showed interest were not mentioned in the paper  |
| Analysis  | Qualitative analysis identified seven key themes from the data including: knowledge, physical and psychological impact, control and trust, catalyst to action, organisation of care and communication, attendance and intervention, expectations and systems. Each session lasted between 30 and 60 minutes and was terminated once saturation was reached. The authors were aware that saturation of the topic may not have been achieved with the limited number of participants ( $n = 7$ ) and so they terminated each interview once individual saturation was reached and themes became repetitive. Audio-recordings of the interviews were listened to on three occasions and transcribed verbatim by the researcher. Data analysis was undertaken utilising the Colaizzi method (with the reference given). Significant statements were then highlighted manually and extracted from the text and formulated into clusters of themes. Connections between the themes and subthemes that were manifest in the data were explored and the data were then condensed into seven emergent themes that gave a comprehensive description of the experience |
| Interpretation  | Evidence of time spent dwelling with the data were provided. Each transcript was read on six occasions as this enabled the researcher to gain greater familiarity with the phenomenon by becoming 'fully immersed and marinated in the data'. Having seven themes allowed for verbatim quotations to be used within the study's results section, increasing the trustworthiness of the interpretation and credibility of the findings, according to the authors. Themes were discussed with the research team until a consensus was reached, in order to verify the reliability of data collection and rigour in the analysis process   |
| Reflexivity   | Eligible participants were selected and approached initially by members of the diabetes mellitus team or by the diabetes mellitus specialist midwife and were involved at their next clinic visit; this shows that the researchers and research team had a relationship with the participants during fieldwork. There was some evidence of negotiations between the team when going ahead with the chosen themes  |



**TABLE 3** Quality appraisal of included studies (*continued*)

| Stages                                       | Narrative summary   |
|--|---|
| Ethical dimensions                           | The protocol was approved by the NRES Committee Northwest-Cheshire (11/NW/0074) and informed consent was obtained from all participants. When and how this was done was not stated. There were no other ethical issues considered and no information on how autonomy, consent, confidentiality and anonymity were managed   |
| Relevance and transferability                | The strengths and the limitations of the study were clearly outlined. The strength of this work is that it featured women in their first pregnancy so each experience was new and there was no bias from previous pregnancy-related episodes. A potential limitation to this study was stated to be that the authors only looked at white women, so the sample population was not ethnically diverse. The results were supported by evidence in the form of quotations. Further areas to investigate, such as teenage pregnancy, were also discussed. Where this study differed to that from literature was also discussed and referenced. The role of the diabetes mellitus team was also explored, along with suggestions as to how it should be implemented. How the current diabetes mellitus teams do not empower patients was discussed along with a closing remark on what the patients need from the care team. Therefore, the significance this study has for current practice and changes to current procedures was outlined. However, as this study looked at a small population, this might not be reflective of all women with diabetes mellitus |
| Short narrative summary of the study quality | Quality assessment: the study consisted of open-ended questions for seven purposely selected participants from a pool of potential participants. There was no real mention of ethics concerns for the participants. Bias was kept low by selecting women who were pregnant for the first time; therefore, previous experiences could not be referred to. Implications of quality assessment: the paper had a clear focus of women's experiences of their first pregnancy and their T1DM. No details on the design used were given   |

CD-ROM, compact disc read-only memory; DVD, digital versatile disc; e-health, electronic health; HREC, Human Research and Ethics Committee; NRES, National Research Ethics Service; NSF, National Service Framework; PhD, Doctor of Philosophy; PRAMS, Pregnancy Risk Assessment Monitoring System; R&D, research and development; SPSS, Statistical Product and Service Solutions; UCL, University College London; UCLH, University College London Hospital; WHO, World Health Organization.

## Analysis of the findings of the included studies

After a detailed reading and rereading of the 18 studies included in the systematic review, four main themes and 12 further subthemes were identified. These themes and subthemes are detailed in *Table 4*, which gives a summary of the key themes emerging from the included studies. The summary of the themes is provided for clarification rather than to weight the themes. Each of these four themes and subthemes is then discussed in more detail.

### *The complexities of pregnancy planning*

The notion of pregnancy planning can be identified as one of the four significant themes to emerge from the analysis of the descriptive literature. Pregnancy planning is a complex phenomenon and this complexity has a bearing on the uptake of PCC for women with pre-existing diabetes mellitus. Of the 18 published studies reviewed, 10 explored the various complexities associated with pregnancy planning and these have been categorised into three further subthemes: (1) problematising 'planned'/'unplanned' pregnancy, (2) the social significance of pregnancy and (3) understanding fertility beliefs. These subthemes are discussed in the following three sections.

### **Problematising 'planned'/'unplanned' pregnancy**

Pregnancy planning is complex because the concept of 'planning' is hard to define. It is interesting to note that most of the published literature reviewed does not provide definitions of 'planned' and 'unplanned' pregnancy and these concepts were seldom problematised. Definitions used in different studies include planned/unplanned pregnancy, intended/unintended pregnancy and wanted/unwanted pregnancy. When definitions were given they varied across publications. For example, the work by Richmond,<sup>40</sup> a phenomenological study of 11 white women with T1DM, is an exception and in this paper the author defines unplanned pregnancy as one in which women 'had not intended having another child at this time and therefore their pregnancies were unplanned'. Only 3 out of the 18 publications reviewed sought to

TABLE 4 Summary of key themes emerging from the included studies

| Study reference                                    |   |
|--|---|
| Themes and subthemes                               | Berg and Sparud-Lundin <sup>26</sup> Chuang et al. <sup>27</sup> Collier et al. <sup>28</sup> Devido <sup>29</sup> Griffiths et al. <sup>30</sup> Holing et al. <sup>31</sup> King and Wellard <sup>32</sup> Lavender et al. <sup>33</sup> McCorry et al. <sup>34</sup> Mersereau et al. <sup>35</sup> Mortagy et al. <sup>36</sup> Murphy et al. <sup>37</sup> O'Higgins et al. <sup>38</sup> Power et al. <sup>39</sup> Richmond <sup>40</sup> Shawe <sup>41</sup> Spence et al. <sup>42</sup> Woolley et al. <sup>43</sup>   |
| The complexities of pregnancy planning             |   |
| Problematising 'planned' and 'unplanned' pregnancy | ✓✓✓ |

| Study reference                                  |  |
|--|--|
| Themes and subthemes                             | Berg and Sparud-Lundin <sup>46</sup><br>Chuang et al. <sup>27</sup><br>Collier et al. <sup>28</sup><br>Devido <sup>29</sup><br>Griffiths et al. <sup>30</sup><br>Holing et al. <sup>31</sup><br>King and Wellard <sup>32</sup><br>Lavender et al. <sup>33</sup><br>McCorry et al. <sup>24</sup><br>Mersereau et al. <sup>25</sup><br>Mortagy et al. <sup>36</sup><br>Murphy et al. <sup>37</sup><br>O'Higgins et al. <sup>38</sup><br>Power et al. <sup>39</sup><br>Richmond <sup>40</sup><br>Shawe <sup>41</sup><br>Spence et al. <sup>42</sup><br>Woolley et al. <sup>43</sup> |
| Meeting women's needs                            |  |
| Effective communication                          | ✓  |
| Providing individualised care                    | ✓  |
| Co-ordination, organisation and delivery of care | ✓  |



fully explore whether pregnancies could be categorised as planned or unplanned, or to problematise the relationship between this and low uptake of PCC among women with pre-existing diabetes mellitus. The three papers<sup>30,31,35</sup> that problematised the concepts of planned/unplanned pregnancy showed how these concepts were not neat categories into which women's motivations and behaviours could be organised.

In setting up their study (which included 85 women with pre-existing diabetes mellitus) and outlining their inclusion/exclusion criteria, Holing *et al.*<sup>31</sup> described planned/unplanned pregnancy as follows:

*A planned pregnancy was defined as a pregnancy that was desired before conception and in which contraception was stopped or avoided for the purpose of becoming pregnant and in which the women stated that she attempted to achieve optimal blood glucose control before becoming pregnant.*

Using this definition, their data revealed that 41% of pregnancies were planned and 59% unplanned. Of the women whose pregnancies were unplanned, 70% had not been using contraception reliably and most were happy to be pregnant. A further 10% revealed that they had in fact been hoping to get pregnant. These findings led the authors to suggest that there is no one factor that could account for the complexities of pregnancy planning in which life experiences and circumstances, together with personal motivations and stresses, come together to influence women's behaviours. However, they argued that 'a crucial factor may be a woman's subconscious desire to be pregnant and that some unplanned pregnancies may not be unexpected.'<sup>31</sup> The authors of this paper concluded by questioning the dichotomy between planned and unplanned pregnancy suggesting that, 'some pregnancies may actually be "subplanned" '<sup>31</sup>

Griffiths *et al.*<sup>30</sup> were also critical of the dichotomy between planned and unplanned pregnancy. In this study, 15 white women with T1DM were interviewed using semistructured interviews and topic guides to explore how women accounted for how they became pregnant. They argued that the terms 'planned' and 'unplanned' were often meaningless to women and rarely used by women themselves. Moreover, they stated that when they asked pregnant women specifically about these terms, the definitions given were conflicted and complex, suggesting that it is not helpful to use these categories to define pregnancy planning. For example, when the women in this study were asked about whether or not they had been using contraception before becoming pregnant, they spoke of forgetting to use contraception and some spoke of pregnancy as being a 'surprise':

**Interviewer:** *So before you became pregnant with [daughter], were you using contraception?*

**Participant:** *Yes and no. Well, it was just where I'd get to the stage where I would keep forgetting to take my tablets or knew where the condoms were . . . We kept both, which . . . It's easily done.*

In conclusion, the authors argued that 'the complex lived experiences of becoming pregnant [. . .] defy categorisation as planned or unplanned' and that most pregnancies fall somewhere in between these categorisations.

Shawe<sup>41</sup> also questioned the dichotomy between planned and unplanned pregnancy, and in the process of data collection and analysis concluded that a far more nuanced approach is required. Shawe's mixed-methods study drew on questionnaire and interview data with 107 with T1DM and 32 women with T2DM, and the focus was on the prevention of unplanned pregnancy. Some of the women in the study, for example, spoke about an 'unconscious desire' to become pregnant:

*The second and third, I wanted to get pregnant at some point but I did not plan as such. I think I thought if it happens then that's ok – sort of an unconscious thing really.*

*Woman with T1DM, p. 255<sup>41</sup>*

It is noteworthy that Holing *et al.*<sup>31</sup> also mentioned that women may have an ‘unconscious desire’ to achieve pregnancy.

Several of the women in Shawe’s study<sup>41</sup> also spoke about pregnancy as something that ‘just happened’ and being within the context of not being able to discuss it openly with their partner or husband. For example, one woman with T1DM in this study said:

*I didn’t mind if I did get pregnant but my husband wasn’t keen and we didn’t really talk about it and then it just happened.*

p. 352<sup>41</sup>

Shawe<sup>41</sup> concurred with other studies conducted in diabetic and general populations to conclude that there is a continuum of planning for pregnancy. She reflected on the utility of the dichotomy between planned/unplanned pregnancy and questioned whether or not the use of these terms may have been a limitation that obscured women’s true pregnancy intentions.

Moreover, Shawe<sup>41</sup> argued that although understandings of planned and unplanned pregnancy may be clear to health professionals and in the context of health policy literature, this understanding is not shared by women. This incongruence between the views of women and those of health professionals was one of the major themes identified in Shawe’s work.<sup>41</sup>

Focusing specifically on the perspectives of health professionals, there is some limited evidence to suggest that health professionals are not fully aware of the nuances concerning planned/unplanned pregnancy. The notion that most pregnancies are unplanned emerged as a major theme in the work of Mersereau *et al.*<sup>35</sup> This study investigated the concerns of health professionals (including physicians, mid-level practitioners and certified diabetes mellitus educators) who care for women with diabetes mellitus in pregnancy. The study included 53 health professionals who participated in six mixed focus groups. Some health professionals in this study thought that all of the pregnancies in their settings were unplanned and across all groups most of the practitioners said that < 10% of their patients with pre-existing diabetes mellitus discussed pregnancy planning with them.

The studies<sup>30,31,41</sup> discussed above demonstrate that notions of pregnancy planning and the concept of planned/unplanned pregnancies are likely to be more nuanced than those expressed by the respondents in the study by Mersereau *et al.*<sup>35</sup> It is of note that most of the literature reviewed here fails to problematise the concept of planned/unplanned pregnancy and to address the incongruence in views between women with pre-existing diabetes mellitus and the professionals who provide their care. Problematising the concepts of ‘planned’/‘unplanned’ pregnancy is significant because these are not terms that women used necessarily and there was no shared meaning among women or between women and health professionals.

### The social significance of pregnancy

Pregnancy planning and defining what is ‘planned’ or ‘unplanned’ can be complex because pregnancy is socially significant. Eight out of the 13 published studies exploring the complexity of pregnancy planning remarked on the social significance of pregnancy within the context of women’s lives and on the relationship between this and the management of diabetes mellitus and PCC.

Holing *et al.*,<sup>31</sup> who set out to determine why women with diabetes mellitus generally do not plan their pregnancies, argued that the desire for motherhood is an integral part of women’s self-identity. This study, which included 85 women with pre-existing diabetes mellitus, noted that, of the 50 women with unplanned pregnancies, 70% said that they were very happy when discovering they were pregnant. It is not clear from the study how many women had T1DM or T2DM and how many women were white or non-white. When women were asked how they would have felt if they had been unable to have a baby,

responses were emphatic stressing feelings of sadness and loss. One woman said that her 'life would be empty. I would have been devastated. It was what I wanted more than anything in the world'. Another woman said that '[it w]ouldn't make me feel like a woman. It's what I was meant to do. It probably never would be OK'.

Commenting specifically on unplanned pregnancies, Holing *et al.*<sup>31</sup> suggest not only that unplanned pregnancies are not 'unexpected' but that 'the situational and emotional factors associated with unplanned pregnancy are complex and deeply rooted'.<sup>31</sup>

In the study by Griffiths *et al.*,<sup>30</sup> women also reported conflicted feelings about pregnancy. Although women's accounts of becoming pregnant varied, some women struggled to reconcile their feelings of ambivalence about their pregnancy. When one of the study participants was asked about how she felt when she found out about her current pregnancy, she said:

*I can't remember. It was all sort of . . . to be perfectly honest with you I would not have had another child if it wasn't for [son]. If it was down to me personally I wouldn't have another one.*

Later in the interview the woman added:

*I think I should stress . . . because it sounded really bad, but this pregnancy . . . I do want as much as we wanted the first time but just for different reasons. It's really hard to explain that without sounding like 'I'm not really that bothered.' You know, we really are.*

This study further demonstrated that women's feelings about pregnancy can be complicated.

For some women with pre-existing diabetes mellitus, pregnancy planning may be further complicated by complex feelings and ambivalence relating specifically to the experience of living with diabetes mellitus or to being pregnant with diabetes mellitus. In the study by McCorry *et al.*,<sup>34</sup> 14 women with T1DM were interviewed about their attitudes to pregnancy and PCC-seeking. The ethnicity of the participant group was not reported. One of four emergent themes in relation to preconception planning was identified as the 'emotional complexity of childbearing decisions'.<sup>34</sup> All of the women included in the study were anxious about childbearing and reported feelings of ambivalence. The authors stated that:

*. . . the balancing of desire for children and fear of the complexities that pregnancy might bring led to increased ambivalence about the decision to have a family.*

The views of two specific women were reported. One woman said:

*I thought complications would be too much. It just sounded like it wasn't worth the risk, either for myself or a new baby, of some sort of damage.*

Another said:

*It's one thing me worrying about causing damage to myself, I can kind of deal with that cause it's only me that's going to reap the repercussions, but, you know, if I'm putting someone else at risk, it's not worth potentially even higher risks.*

As the authors concluded, what was especially interesting about these data was how ambivalence around childbearing had consequences for women's reproductive behaviours, including whether or not they sought PCC.

Chuang *et al.*<sup>27</sup> also reported that pregnancy intention could be affected by feelings about living with diabetes mellitus and the impact of this on pregnancy. They argued:

*... many [...] women with diabetes expressed increased ambivalence or decreased intent for future pregnancy because of the risks posed by their conditions.*

They quoted one woman who expressed concern about her ability to care for a child while also feeling 'burdened' by having to take care of herself:

*just getting up and dealing with diabetes for 35 years in a row is just exhausting and I just could not imagine having to get up in the morning and have somebody else to have to take care of on top of myself.*

This study included 72 women with chronic conditions (diabetes mellitus, hypertension and obesity), of whom 16 had pre-existing diabetes mellitus, and it is mostly clear when findings related to the experiences of women with diabetes mellitus. The findings of the study are relevant because they show interesting similarities and differences between women with different conditions. Women with diabetes mellitus were particularly likely to have decreased intent for future pregnancy but were aware of the need for glycaemic control if they were thinking about planning a pregnancy.

The paper by Richmond<sup>40</sup> focused on the significance of pregnancy and motherhood for women's self-identity. This work, which attempted to show an 'inner perspective on being diabetic and pregnant',<sup>40</sup> investigated how glycaemic control might relate to identity and social roles. The author argued that living with diabetes mellitus caused 'dilemmas for both self and identity',<sup>40</sup> and they identified a range of identities, or social roles, that determined how women feel and behave in relation to pregnancy. These roles included 'mother', 'compliant patient', 'diabetic', 'partner', 'rebel' and 'self'. Of particular relevance to the complexity of pregnancy planning and the social significance of pregnancy is the resentment reported by women who had been diagnosed with diabetes mellitus as children or teenagers. This resentment played a role in how far they were willing to comply with medical advice. One of the women was reported as saying:

*I had a pretty wild life ... but em looking back there was a couple of times due to ... excess alcohol intake, I'd say that I could have died ... It was stupid to do that if you're not diabetic, but being diabetic, it was incredibly stupid ...*

Although the author was not able to draw conclusions about different sorts of identity types, it is of interest because it highlights the importance of the relationship between identity and compliance with health-care regimens, specifically in relation to diabetes mellitus in pregnancy.

The literature discussed so far demonstrates that the emotional complexities surrounding pregnancy and ambivalence regarding living with diabetes mellitus in pregnancy can mean that women with pre-existing diabetes mellitus feel conflicted about pregnancy planning. The literature shows that these feelings can be further compounded by social and cultural norms that determine when it is considered to be the 'right time' to become pregnant and become a mother.

In Shawe's<sup>41</sup> doctoral work, she described how some (particularly younger) women felt about being offered unsolicited advice on PCC. Women remembered advice being offered but felt that it was not relevant to them at the time because they felt they were 'too young' to have a baby. One woman with T1DM recalled the following:

*Oh – I think they might have said come back if you ever decide that is what you want to do sort of thing [get pregnant].*

p. 224<sup>41</sup>

A woman with T2DM said:

*Well nothing much – when I told her I was getting married, did say to talk to her if I wanted to get pregnant as there could be complications but that's all really.*

p. 224<sup>41</sup>

Neither of these young women felt that pregnancy was relevant to their circumstances at the time and, therefore, did not need to discuss the issue with a health professional.

In the study by Griffiths *et al.*,<sup>30</sup> the research participants also discussed ideas about when was the 'right time' for them to become pregnant. Like the women in Shawe's<sup>41</sup> work, one woman in the study described herself as being 'too young':

*I was hoping to get pregnant later in life because we were still young, but I don't regret it now . . .*

The women in the study also discussed ambivalent feelings about becoming pregnant and whether or not they were 'ready' to be a mother:

*We were trying to save up some money [for a holiday] [. . .] which I was looking forward to until I found out I was pregnant with my first child [. . .] I wasn't quite sure if I was ready to be a mother, but now I'm a mum I'm pleased . . .*

Women also discussed ideas about pregnancy and pregnancy planning within the context of their own experiences of family size and what they thought was most desirable, for example:

*Well baby number three was a bit of a surprise. I said that I would very much like to have three children because I am one of three, my husband is one of two and once we had a boy and a girl he was quite happy . . .*

The literature suggests that some women may also feel pressure to conform to external pressures regarding the social or cultural ideals about the right time to have a baby. This feeling was expressed by two of the women in the study by Lavender *et al.*<sup>33</sup> This was one of the few studies to include women of non-white origin and specifically included 22 women with T1DM and T2DM of white and South-East Asian origin. One Asian woman who accessed PCC reported feeling 'pressure from outside' to have a baby. She said:

*. . . in our culture, once you're married, it's babies, you know and I've been married for three years now and it's all been expected. I mean it's three years [. . .] too late now [. . .] I mean, why is she not having kids?*

The article also reported that another woman of South-East Asian origin wanted to conceive a male infant despite being told that pregnancy was a risk to herself and given medical advice not to get pregnant. The authors concluded that:

*Preconception services should include recognition of socio-cultural differences and be sensitive to women's desires to have an infant as well as optimising diabetes well-being.*

The article by Spence *et al.*<sup>42</sup> showed that ideas about when it is the 'right time' to have a baby are also shared and expressed by the health professionals who provided care to women with diabetes mellitus. This study focused on exploring the knowledge and attitudes of 24 women with T1DM and T2DM towards PCC. Drawing on data generated via focus groups, the authors noted that women were more likely to be asked about planning for pregnancy if they were engaged or married, arguing that this 'confirmed

preconceived ideas and social stereotypes held by their health professional'.<sup>42</sup> The data reported in the study suggest that some women were able to challenge these preconceived ideas, for example:

*The second they spotted an engagement ring, they said 'Are you planning a pregnancy?! Well, maybe I would have had one before I was engaged. Like I'm 27, so . . . just because there's an engagement ring on my finger doesn't mean all of a sudden I'm going to have a baby!*

Ideas about the 'right time' to have a baby and become a mother were felt keenly by women. They articulated these ideas within the context of their own lives, experiences and circumstances. They also reported feeling the pressure of the cultural and social norms held by family and community, as well as by health professionals. Together with feelings of general ambivalence and conflicted feelings about diabetes mellitus in pregnancy, the literature highlights the complexity of pregnancy planning and the relationship between this and PCC.

### Understanding fertility beliefs

Fertility beliefs, which can be defined as lay understandings of pregnancy and childbearing, are also important in determining women's relationship to pregnancy and PCC. Given the social significance attributed to pregnancy and motherhood that was reported in the literature, it is not surprising that many women regard conception and pregnancy as a unique part of a woman's life and subject to particular ways of knowing and understanding. Five out of the 13 studies that discussed the complexity of pregnancy planning explored the importance of fertility beliefs.

Two out of the five studies that discussed the importance of fertility beliefs explored the idea of pregnancy as a private experience, rather than a public one. For example, in one study,<sup>33</sup> women who were aware of the availability of PCC were often reluctant to attend because they wanted the pregnancy to remain a private matter. The authors stated that this was either because women did not want the inconvenience of taking time off work and having to provide an explanation for absence, or because they had not enjoyed the experience on a previous occasion. One of the respondents in this study said:

*It's such a private thing, isn't it? . . . just to attend a clinic you have to tell work where you're going . . . you think I've got to tell a few white lies because I don't want them to know that we're trying [to conceive] and things like that.*

In another study,<sup>41</sup> the author reported similar findings. She argued that some women felt that trying for a baby was a private, intimate issue and not one to be discussed within a medical environment such as a hospital.

For some of the women in this study, pregnancy was not just a private issue but also a magical experience. One woman said that pregnancy planning, ' . . . takes the magic away'.<sup>41</sup> The author suggested that such women had 'romantic notions' of becoming pregnant that were in contrast to more clinical views of pregnancy planning and PCC. Pregnancy planning and discussing conception was also thought to 'spoil', or even harm, the experience of getting pregnant. Another woman in this study said:

*We'd always said that we'd like to get pregnant without really trying, so luck was with us . . . I think it can spoil things and if you are always thinking about it and worry that it won't happen.*

p. 261<sup>41</sup>

In the study by Chuang *et al.*,<sup>27</sup> slightly different fertility beliefs were expressed. Here women expressed the belief that planning a pregnancy was not really within their control. One of the women in this study compared planning a pregnancy to being able to control the weather:

*So I mean yes, I would have loved to have planned it, but you know for me it would have been like trying to plan the rain . . .*

Another woman also expressed some scepticism about the ability to plan:

*I'm kind of already being a little more attentive to trying to check my sugars more often so that I can keep my A1C [glycated haemoglobin] lower. I mean you know it is like we may have our plans, but we all know how that goes . . .*

Some women in the study by Chaung *et al.*<sup>27</sup> also made reference to fate and to religious beliefs, including reference to God and the divine.

Another significant aspect of women's fertility beliefs relates to the view that women with pre-existing diabetes mellitus will find it difficult, if not impossible, to get pregnant, or that achieving conception will take longer than it would otherwise. This view was reported in three of the published studies in this systematic review.<sup>31,37,41</sup>

Murphy *et al.*<sup>37</sup> explored the views of 29 women who did not attend PCC; 21 of these women had T1DM and eight had T2DM. Drawing on data from semistructured interviews, the findings of this study revealed that one-third of the women believed that they would not get pregnant because they either had high blood glucose levels or perceived fertility issues. Three of the women described how they became pregnant when their glycaemic control improved, and two of these are reported here. One woman said:

*Because I didn't ever think that I would be able to have children. I just thought that that was a lot harder to conceive with having diabetes.*

Another said:

*You can't, apparently so, really conceive when you've got high blood sugars . . . Your body's just not able to function properly and . . . I don't know the reason for it really . . . and then my sugars came down and I did get pregnant.*

In the study by Holing *et al.*<sup>31</sup> a similar picture is reported. Nearly half of the women with unplanned pregnancies who did not use contraception believed that they were unable to become pregnant. Various reasons were reported for this, including being told that their partner was sterile, believing that diabetes mellitus made it more difficult to conceive and believing that they could not conceive because they had not become pregnant on prior occasions when not using contraception. The authors report that none of these women had undergone a fertility evaluation or received a medical diagnosis to confirm infertility. Although this study reported descriptive data, no descriptive data were given for this theme.

In Shawe's<sup>41</sup> study, women with T1DM also talked about how difficult it could be to become pregnant with poor glycaemic control. Here women also mentioned the relationship between high blood glucoses and pregnancy loss. For example:

*I think it is harder to get pregnant and stay pregnant if you have bad sugars.*

*p. 252*<sup>41</sup>

However, not all of the women shared these fertility beliefs. Some women did not think that diabetes mellitus affected fertility or had not given it any thought at all. One woman with T1DM was not aware of any problems:

*No – I had no trouble getting pregnant.*

*p. 252*



A woman with T2DM and another with T1DM had not considered the relationship between diabetes mellitus and (in)fertility:

*Oh can it – I hadn't thought about that?*

*No I had never got round to thinking about that as they were all unplanned.*

p. 252

In her study, Shawe<sup>41</sup> also spoke with health professionals. These interviews revealed that some were aware of women's fertility beliefs and that it was important to address this when giving advice:

*... some of them may think that it's more difficult when they've got diabetes, but it isn't and for me it's important to let them know that it's just as easy for them to get pregnant but also much more risky for the baby ...*

p. 252<sup>41</sup>

The published literature reviewed here indicates that fertility beliefs may be important in relation to uptake of PCC for three main reasons. First, pregnancy is sometimes regarded as something that is private, special and unique and not something necessarily to be discussed publicly; this may influence the likelihood that women will wish to discuss pregnancy planning with a health professional. Second, romantic notions of pregnancy, in which getting pregnant is seen to be the work of fate, luck or the divine, can also influence whether or not women consider pregnancy planning because getting pregnant is regarded as something outside their locus of control. Third, beliefs about how difficult it can be to get pregnant when living with diabetes mellitus also seem relevant and might mean that women are less rigorous in taking contraceptive precautions or less likely to raise the topic with health professionals for fear that the discussion will be futile.

### **Knowledge of pregnancy planning, diabetes mellitus and risk**

There is evidence in the published literature that women's knowledge of pregnancy planning, pregnancy and diabetes mellitus and the risks associated with this is variable but that women's knowledge is significant in relation to preparedness for pregnancy and their potential or actual uptake of PCC. Out of the 18 published studies in this review, 14 contained data pertaining to women's knowledge of pregnancy planning, diabetes mellitus and risk and/or the views of health professionals. The analysis of these 14 studies is organised into three subthemes, which are discussed below: (1) knowledge about contraception, (2) knowledge about risk factors and lifestyle and (3) knowledge about PCC.

#### **Knowledge about contraception**

Fertility beliefs can strongly influence contraceptive use. Contraception is an important part of managing fertility and pregnancy planning but the literature indicated that women's knowledge about contraception varied. Out of the 14 studies that discussed knowledge of pregnancy planning, diabetes mellitus and risk, five papers explored knowledge about contraception.

Three studies<sup>27,37,41</sup> explored women's knowledge and understanding of birth control options. One group of authors argued that regardless of parity, the women included in their study were often unaware that their birth control options might potentially be limited by their condition.<sup>37</sup> When women were asked about whether or not they thought certain types of birth control might be less safe for them, they responded either that there were no safety issues or that they had not considered it. The authors of this study made an interesting point here but no descriptive data from women with pre-existing diabetes mellitus were presented to support their assertion.

In contrast to this, the other two studies<sup>27,41</sup> reported that some of their participants were aware that certain birth control options might be contraindicated. Four of the women in the study by Murphy *et al.*,<sup>37</sup> which included women with T1DM and T2DM, said that they believed they were not able to take the contraceptive



pill because of their condition. In two of these cases, the women had experienced miscarriage, and one woman reported a recurrent history of serious adverse outcomes. One of the women in this study stated:

*Well, em, initially, when I was first diabetic I was told that I couldn't take the pill anymore because it was . . . the risk factors were too high.*

While another said:

*Well my doctor didn't give me the pill . . . No, 'cos I've got diabetes and you know, I'm not the most em, the best diabetic I think. I've had it such a long time so, I don't look after myself the way a lot of people do.*

Shawe<sup>41</sup> also reported that some of the women in her study felt restricted in their choice of birth control. One of the women interviewed with T1DM was clear that she had been told by her GP that she would not be allowed to use hormonal methods of contraception because of her diabetes mellitus. She felt that this severely restricted her choice of contraception and subsequently relied on barrier methods only.

There were several other comments in Shawe's questionnaire that supported the notion that women with pre-existing diabetes mellitus may feel restricted in their choice of contraception. It is not clear from the study whether these women had T1DM or T2DM.

Some of the women in the study by Murphy *et al.*<sup>37</sup> also spoke of the side effects associated with the use of hormonal contraceptives, such as mood disturbances, dysfunctional bleeding and amenorrhoea, and this meant that women discontinued using these forms of birth control. The authors conclude that women had:

*. . . difficulties complying with contraceptive advice, with 70 per cent [of the women in their study] not taking reliable effective contraception prior to becoming pregnant.*

The fact that women with diabetes mellitus might feel restricted in their choice of birth control and less likely to use hormonal methods of contraception was further reinforced by some of the interviews with health professionals.<sup>41</sup> Shawe<sup>41</sup> argued that health professionals are often aware that women believe that they cannot take hormones. Health professionals who worked in secondary care settings felt that GPs are often reluctant to prescribe hormonal contraception to women with pre-existing diabetes mellitus even when that approach might not be necessary.

The view of not prescribing hormonal methods of contraception to women with diabetes mellitus was seen as 'old-fashioned' or out of date by several other respondents too.

Although these professionals acknowledged that advancements in medication and hormonal contraceptives means that women with pre-existing diabetes mellitus can be prescribed hormonal contraception, the data reported by three studies<sup>27,37,41</sup> highlighted that women feel restricted in their choices of birth control. The impact of this real and perceived restriction may have an effect on women's contraceptive decisions.

The more realistic risk of other medications interacting with contraception and reducing its efficacy was also discussed in two of the studies reviewed<sup>37,41</sup> and mentioned by McCorry *et al.*,<sup>34</sup> who argued that ' . . . another barrier to preconception care arises when a woman does not use contraception effectively'.

In the study by Murphy *et al.*,<sup>37</sup> three of the women with unplanned pregnancies denied problems with compliance and argued that contraceptive failure and/or interactions with medications had caused them to become pregnant. In the same study, four women with T2DM described the unanticipated effects of medications and/or weight loss on their fertility. For example:

*It was antibiotics that got in the way of the pill and that's what happened.*

*I was on the contraceptive pill . . . Yep and, but I was also taking em, oh what was it called, Reductil . . . I was still taking the [Reductil] tablets and metformin the day I got pregnant.*

In Shawe's<sup>41</sup> study, interactions between latex-based barrier methods of contraception (such as latex condoms or the latex diaphragm) and vulvo-vaginal medications were discussed, the latter having a weakening effect on the latex, therefore reducing efficacy. Shawe<sup>41</sup> pointed out that women with diabetes mellitus with high glucose levels are more vulnerable to candida infection and that antifungal treatments could interact with latex.

However, when women were asked whether they had received any information about latex condom use and the use of antifungal medication, none of them said that they had been given information by their GP, a health professional, or pharmacist and did not know about the potential interaction and reduction in contraceptive efficacy.

Murphy *et al.*<sup>37</sup> also noted that several of the women with T2DM in their study had been prescribed medications [e.g. metformin hydrochloride or rosiglitazone (Avandia®, GlaxoSmithKline, Brentford, UK)] that are known to enhance ovulatory function. Women did not indicate any awareness that increased contraceptive vigilance would be needed to prevent an unplanned pregnancy. As one woman in the study commented:

*I went on to insulin and I was on insulin for a year or 2 trying to have a baby and they said they didn't think I could . . . then . . . they put me on a tablet [rosiglitazone] and 7 years later I'm pregnant . . .*

Although this study included women of white British and Asian backgrounds, this is not reported clearly with respect to the descriptive data presented.

Regardless of what women might know or recall about contraception and diabetes mellitus, the significance of family, culture and relationships in contraceptive use was highlighted by two of the five studies that explored contraceptive knowledge. In the study by Murphy *et al.*,<sup>37</sup> which included women with T1DM and T2DM and women of white British and Asian origin, three out of the six Asian women respondents discussed the importance of their religious beliefs and/or their husbands' views on contraception. One husband described encouraging the use of contraception:

*We're not allowed to use anything like that but we're not strictly you know . . . sticking to religion. We do use it 'cos . . . we're not that religious.*

In contrast, one of the women described being discouraged to use contraception by her husband:

*Yes I was given information by my GP's nurse, but I did not use contraception . . . My husband said, do not use any contraception we want a baby.*

The same study<sup>37</sup> highlighted that some women did not take contraception rigorously, despite knowing that they should, but that this was influenced by personal and/or relationship difficulties. One of the women said:

*It was a lot to do with the relationship I was in as well, sort of like breaking up with him and I was . . . 'I can't be bothered any more to do that'.*

While another said:

*I'd a bit of a bad patch for a couple of months and, you know blood sugar levels went up a bit, down a bit and hence me pill as well. Wasn't takin' it as regular as I should have done.*

Slightly different accounts of how relationships could influence contraceptive use were given by women in the study by Shawe.<sup>41</sup> In this study, women discussed the fact that husbands were not always very 'keen' on having babies so contraception was not necessarily something that was talked about openly. Contraceptive use might be stopped but planning a pregnancy was not discussed. One woman in the study with T1DM said:

*I didn't mind if I did get pregnant but my husband wasn't keen and we didn't really talk about it and then it just happened.*

p. 256<sup>41</sup>

Given that many women with pre-existing diabetes mellitus have 'unplanned' pregnancies, it is important to understand women's knowledge about contraception. Three key issues can be determined from this systematic review about women's knowledge and are discussed in *Knowledge about risk factors and lifestyle*.

### Knowledge about risk factors and lifestyle

The studies reviewed show that women could be knowledgeable about the risks of pregnancy in diabetes mellitus and aware of the range of modifiable lifestyle changes that might be of benefit. However, knowledge was variable and not always very specific. Of the 14 studies concerned with knowledge and understanding of pregnancy planning, diabetes mellitus and risk, 12 discussed knowledge of risk factors and/or lifestyle in particular.

O'Higgins *et al.*<sup>38</sup> drew on the findings of a participative research project to argue that lack of knowledge may be key to understanding why women do not use PCC. In this study, a participative research method called the 'participative research process' was used to facilitate 14 women with pre-existing diabetes mellitus to create 'webs of ideas' on the reasons for attending or not attending a specific prepregnancy care programme. The research included 10 women with T1DM and four women with T2DM, some of whom had attended PCC services and some of whom had not. All of the women were white and Irish. The authors suggested that a '[l]ack of understanding of the risks of poorly controlled diabetes on pregnancy outcome was considered crucial for those not attending'.<sup>38</sup>

With respect to this, one of the women in their study said:

*Mothers unaware of the effect diabetes has on babies' growth.*

And another said:

*Lack of awareness of risk of real complications – may not want to know and afraid to find out how bad it could be for baby.*

In two of the studies reviewed,<sup>27,42</sup> nulliparous women, in particular, were seen to lack knowledge about the risks of diabetes mellitus in pregnancy.

In one study,<sup>42</sup> which included both women with T1DM and those with T2DM, it was argued that nulliparous women did not realise the 'full extent' of pregnancy-related risks unless they specifically sought out advice on this. One of the women in this study (with T1DM) described the moment when she was told that her baby would not survive but said that she had not been aware of the risks involved:

*I got a scan and I was told the baby's not going to survive – multiple abnormalities . . . I later found out, through my own research, that this was due to high blood sugars in early pregnancy. It's . . . I never knew those sorts of things could happen.*

Another woman, also with T1DM, said that she was aware of the need to plan a pregnancy but did not understand why:

*The thing they most wanted to tell me about at this age [20 years] was to use some form of contraception, because you don't want to get pregnant without it being planned . . . but they don't say why it needs to be planned.*

In another study,<sup>27</sup> a similar pattern was found, although descriptive data were not presented for this specific claim. Of the 16 women with pre-existing diabetes mellitus included in this study (out of 72 women with a range of chronic conditions), nulliparous women were less knowledgeable about the risks of diabetes mellitus in pregnancy than parous women. Nulliparous women, they argued, were generally aware of increased pregnancy-related risks, but were unaware of the specific risks to mother and baby. In contrast, parous women were aware that they might have larger babies and that their babies could have blood glucose abnormalities. In addition, parous women were aware of the teratogenic effects of diabetes mellitus medication in pregnancy. One parous woman mentioned the risk of fetal cardiac complications but none of the women mentioned other risks of fetal abnormality.

Of the five published studies reviewed that explore the perspectives of health professionals, only Mersereau *et al.*<sup>35</sup> commented on the issue of knowledge of risks. However, when practitioners were asked about the barriers women might face when managing diabetes mellitus in pregnancy, they grouped their perceptions about barriers into three main categories, one of which was a 'lack of knowledge and awareness'. However, in contrast to the work of Spence *et al.*<sup>42</sup> and Chuang *et al.*,<sup>27</sup> who focused on the knowledge of nulliparous and parous women, Mersereau *et al.*<sup>35</sup> argued that women with T2DM are the least knowledgeable about the risks of diabetes mellitus in pregnancy. One practitioner was quoted as saying:

*The type 2s especially . . . haven't been educated on the importance of getting their blood sugars in control prior to getting pregnant and getting prenatal care started.*

Regardless of parity and type of diabetes mellitus, two further studies<sup>33,34</sup> attributed this lack of knowledge to a deficiency in the information being provided to women by health professionals. One study<sup>33</sup> argued that a lack of knowledge could contribute to a general apathy towards PCC because women did not understand how important it could be to them. The authors stated:

*The general apathy towards preconception care was influenced by a lack of information and/or a lack of emphasis from professionals on the importance of attendance.*

When asked about what they knew and what information they had received, one woman in this study said:

*When I came, we just had vague chats about it to be honest.*

And another woman said:

*I didn't know things like that existed . . . I didn't know anything like that, you know was available to you and I wouldn't have even of known who to ask or where to go or . . . I wouldn't have had a clue.*

In another study,<sup>34</sup> 10 out of the 14 women with T1DM interviewed said that they had limited knowledge of diabetes mellitus in pregnancy. The women attributed this lack of knowledge to a lack of information and, moreover, talked about the anxiety and fear that this engendered. Two of the women in this study said:

*. . . but I have a fear, I suppose I need to weigh things up. It's just like the unknown . . . you need information, so that you can make the decision in your own way, 'cos everybody's different. I'd be scared of the unknown.*

*They don't give you any information about pregnancy or anything, you know. If your overall control's good, and that's really just it . . . at least if people actually know what those risks were before they planned the pregnancy rather than it all being a little bit woolly.*

In this study, the authors highlighted that anxiety and fear could be attributed to a lack of detailed knowledge about diabetes mellitus in pregnancy and what the specific risks might be. Many of the studies reviewed explored women's fears and anxieties in more detail. In the nine studies<sup>26,28,30,32–35,38,40</sup> that explored this, women's concerns could be categorised into three main areas: (1) concerns for themselves, (2) concerns for an unborn child and (3) concerns for existing children. The literature suggested that some women were concerned about one, two or all three of these issues.

Five studies discussed the specific issue of women's concerns for themselves. Richmond<sup>40</sup> noted that women were concerned by a range of issues, including frequency of blood testing, the need to constantly juggle insulin doses, nausea and vomiting, and the risk of hypoglycaemia. In the study by Berg and Sparud-Lundin,<sup>26</sup> one woman was so fearful of hypoglycaemia that she feared dying:

*And sometimes in the evenings I was like . . . I don't know if I dare go to bed, what if I die in my sleep and my husband doesn't notice anything? That really gives you a lot of anxiety, you don't know how you're going to survive.*

All of the women in this study had T1DM and the authors of the study set out to explore the need for, and experiences of, professional support during pregnancy and childbirth. Data were generated via focus groups and interviews. Reporting on the views of health professionals, Mersereau *et al.*<sup>35</sup> argued that health professionals are aware of women's dislike of blood testing and use of insulin. One of the health professionals included in this study said that 'They're more concerned about are they going to have to take insulin . . . They don't want to check their sugars'.

The respondents in this study also stated that women were often concerned about childbearing. One health professional said 'Another thing that I frequently hear is, 'Am I going to have to have a C-section [caesarean section]?'.

This was also identified in the work of Lavender *et al.*<sup>33</sup> but this time it was a concern voiced by the women themselves. Of the 22 white British and South-East Asian women with T1DM or T2DM included in this study, all but one assumed that they would have to have a caesarean delivery. However, none of the women seemed to have had the opportunity to discuss choice of birth method. One respondent in this study said:

*. . . someone's briefly mentioned that I'll probably have it a couple of weeks early. I'm surmising I'll have a caesarean then [laughs] I can't surmise anything else. Erm, but nobody has really gone into details with that.*

It is interesting to note that the Asian women in this study were more afraid than the white British women of having a caesarean delivery. One woman said 'I am scared of having an operation; everything is different here than India'.

In the study by McCorry *et al.*,<sup>34</sup> all of the respondents were generally anxious about childbearing, with the most frequently cited risk being 'having a large newborn'.

In seven<sup>28,32–35,38,40</sup> of the studies, discussion focused on women's specific anxieties and concerns about the health of their unborn fetus or future baby. Based on their study of health-care practitioners, Mersereau *et al.*<sup>35</sup> stated that the concerns practitioners hear from women are generally focused on the health of their unborn baby. One health-care practitioner said:

*Is the baby going to be safe because of the diabetes? They just have that overall fear. They're concerned, they're worried, and they want [baby] to be safe, but they can't articulate what safe is.*

The literature that focused on women's own views supported the idea that many women were generally concerned about having a healthy baby. This was reported in three studies.<sup>28,32,40</sup> King and Wellard<sup>32</sup> conducted seven in-depth interviews with women with T1DM living in rural Australia. They stated that:

*... women reported being motivated to be as healthy as possible and ensure the best outcomes for their baby. The focus was on having a healthy baby.*

Another study<sup>28</sup> concurred with these findings, arguing that a desire for a healthy baby is 'a powerful motivating factor'.<sup>28</sup> One of the women in this study described how she was motivated by this during pregnancy:

*I had to shoot myself with a needle and prick my finger all day. I hated it, hated every minute of it. If my child did not depend on me taking this needle and insulin every day, I would not have done it.*

Concern for the well-being of their babies caused women considerable stress and anxiety. The literature suggests that, although a general feeling of anxiety persists, some women are able to articulate more specific worries and concerns, demonstrating more knowledge of the risks of diabetes mellitus in pregnancy. According to King and Wellard,<sup>32</sup> women in their study expressed concern about their baby being born with an abnormality, dying in utero or being sick and needing medical care after birth. This was supported by another study<sup>34</sup> that also cited malformations and stillbirth as two major concerns for women. O'Higgins *et al.*<sup>38</sup> also point out that the participants in their study knew that 'the health of the mother and glucose control were crucial for a safe pregnancy and a healthy baby free from congenital malformations'. One woman said that it was important to 'get their HbA<sub>1c</sub> [glycated haemoglobin] good, and have a tighter control for the health of their baby'.

The subject of malformations was also explored in the study by Lavender *et al.*<sup>33</sup> In this study, which included white British women and women of South-East Asian origin, South-East Asian women were so concerned about the issue of congenital malformation that they were unable to think about the forthcoming birth of their babies. One South-East Asian woman said:

*Is my child gonna be all right, when I give birth to it? Is it gonna have all its limbs? It's just the thought, it just makes you scared and I just think if I stay pregnant it's alright ... I won't be able to see it ...*

The same study also highlighted that women were concerned about the risk of stillbirth and the death of their baby in utero.<sup>33</sup> The authors reported that women used language that reflected their detachment from their infants, indicative of their uncertainty. Highlighting this point, one of the white British women in this study said:

*... it's more miscarriage, it's more stillbirth ... I'm frightened you just have to wait and see if something really horrible happens to it [baby] but you just do your best to try and make sure that it doesn't.*

Although most of the studies reported that women were concerned about the risks to themselves and to their unborn children, two of the studies identified women's concerns for existing children.<sup>34,40</sup> In one of these studies,<sup>34</sup> a woman reflected on her concerns in relation to her son:

*It just sounded like it wasn't worth the risk, either for myself or a new baby, of some sort of damage. And we had 1 healthy son, and it wasn't going to be fair on him if we had something else along that wasn't just as healthy.*

In the context of the risk of diabetes mellitus in pregnancy, many of the studies explored the issue of lifestyle change. Women were often asked what lifestyle changes they had made in preparation for pregnancy or what lifestyle choices they thought might be important in preparation for another pregnancy. Eight<sup>26–28,30,32,41–43</sup> of the publications reviewed discussed women's knowledge of lifestyle change.

In almost all of the studies ( $n = 7$ ), women seemed aware of the need to address blood glucose levels prior to pregnancy.<sup>26–28,30–32,41</sup> It was an issue about which most women were aware and on which most women had either received or sought information. For example, one of the women with T1DM in Shawe's<sup>41</sup> study described how she carefully monitored her blood glucose levels before becoming pregnant.

Some of the women in Shawe's study<sup>41</sup> sought advice from health professionals whereas others had not. The women in the study by King and Wellard<sup>32</sup> also sought to control their blood glucose levels before pregnancy and the authors reported very high levels of motivation among women. Some women monitored their blood glucose levels with the support of a health professional, whereas others did not. One of the participants in this study said:

*It took 2 years of planning and preparation before my HbA<sub>1c</sub> level was satisfactory. The specialist said after a year that I could go ahead but just from my own research, I didn't like the margins that I had. It was too close for me.*

Another study<sup>26</sup> reported similar findings, arguing that:

*The women had to different degrees, before and during pregnancy, been prepared by the care providers for the need to achieve normoglycaemia.*

One woman from this same study described how she carefully prepared for pregnancy even though she did not normally take such good care of herself:

*I was very careful about that when we were planning to get pregnant. And then I felt great during the entire pregnancy and was really careful about my glucose levels, which I'm not always otherwise.*

The importance of taking folic acid supplementation was also highlighted by several studies.<sup>27,30</sup> Shawe<sup>41</sup> also commented on this. When asking women about what changes they may have made in promotion of a healthy pregnancy, some talked about folic acid.

However, the author noted that, although women might be generally aware of the need for folic acid supplementation, they may not be aware that over-the-counter folic acid may not provide them with the levels required by women with pre-existing diabetes mellitus and available on prescription in the UK.

Changes to diet and exercise and reduced alcohol and cigarette consumption were also discussed in the published literature. As noted above, King and Wellard<sup>32</sup> reported that the women in their study possessed high levels of motivation to achieve a healthy baby; this meant that women were willing to be 'strict' with their diet and lifestyle, as well as with their blood glucose levels. Chaung *et al.*<sup>27</sup> also highlighted that, regardless of pregnancy experience, women felt that lifestyle changes were important and considered smoking cessation and moderation of alcohol to be part of pregnancy planning. Collier *et al.*<sup>28</sup> also stated



that the women in their study were '... following the diet and exercise recommendations that they received in their previous pregnancy'.

However, it was not clear if this assertion applied to women with all types of diabetes mellitus as no descriptive data were presented for women with pre-existing diabetes mellitus. Spence *et al.*<sup>42</sup> suggested that women with T2DM are more likely than those with T1DM to focus on the importance of diet and lifestyle changes. In another study,<sup>43</sup> women recognised the importance of lifestyle for a healthy baby only in retrospect. The aims of this study were to explore women's perceptions and experiences of being pregnant; the findings drew on a purposive sample of seven women with T1DM in their first pregnancy. Women sometimes described themselves as 'lazy' and needing to 'get off their backside':

*... It's just laziness and ... it wasn't that I couldn't be bothered, it was I'll behave me'self tomorrow, I'll get on top of it next week an' there's always been an excuse ... It took getting pregnant for me to do this ... to get me off my backside ...*

However, Woolley *et al.*<sup>43</sup> argued that women felt that the lifestyle changes they had managed to make during pregnancy were likely to continue and go on to improve their health in the longer term.

Knowledge about the risks of diabetes mellitus in pregnancy emerged as an important subtheme that helped explain women's views and experiences of pregnancy planning. The findings of the studies reviewed shows that knowledge varied considerably and some women had a general awareness of the risks involved but were lacking in specificity. The risks of diabetes mellitus in pregnancy caused women considerable worry. Anxieties were centred around concerns for their own well-being, including concerns about childbirth, concerns for their unborn child or future baby and concerns for existing children.

### Knowledge about preconception care

Knowledge about PCC is also an important subtheme and was addressed in 10 of the studies. The literature focused on whether or not women were aware of the existence of PCC services and, if they were, the circumstances under which women were most or least likely to use those services.

Some women may not attend PCC simply because they do not know about it. Three of the studies included in this systematic review came to this conclusion.<sup>33,38,41</sup> The first study<sup>38</sup> asked women about non-attendance at a specific pregnancy preparation programme and found that a lack of awareness of its existence was a major factor. However, they noted that prior positive experiences meant that they were more likely to attend in the future. In the second study,<sup>37</sup> three of the women they interviewed were completely unaware of the existence of PCC. The third study<sup>33</sup> also supports this conclusion. One of the white British women interviewed in this third study said:

*Erm, but I didn't know things like that existed ... I didn't know anything like that, you know was available to you and I wouldn't have even of known who to ask or where to go or ... I wouldn't have had a clue.*

According to the authors, South-East Asian women were even less likely than white British women to know about the existence of preconception.<sup>33</sup>

Shawe<sup>41</sup> argued that, from the point of view of health professionals, pregnancy planning equated with PCC but that for many women this was simply not the case. That is, Shawe argued that there was an incongruence between women's definition of pregnancy planning and the definitions expressed by health professionals or found in health policy documents. This was exemplified by the fact that, although some women did not attend PCC because they were not aware of it, other women were aware of PCC but did not avail themselves of it. An analysis of the four studies<sup>28,30,34,37</sup> that explored this issue showed that this was either because women did not think it was relevant or important to them or because they already considered themselves to be knowledgeable on the subject of pregnancy planning. In the study by Collier



*et al.*,<sup>28</sup> very few women thought that attendance at PCC was a strategy for having a healthy pregnancy. Likewise, in the study by McCorry *et al.*<sup>34</sup> a similar pattern was found. They referred to the example of one woman who had experienced a previous pregnancy complicated by diabetes mellitus but who still failed to see that PCC might be useful or relevant. The woman said:

*I don't really know why I would speak to my doctor before getting pregnant. I would definitely go to see her if I knew I was definitely pregnant. I don't really know if I'd plan ahead. I can't really say that definitely I would do things differently.*

Other women may not attend PCC because they already consider themselves to have the appropriate expertise. Some of the women who participated in the study carried out by Griffiths *et al.*<sup>30</sup> made this point. They felt that, as they were already proficient in managing their own diabetes mellitus, they needed no additional advice on preparation for pregnancy. When women were asked about how they had informed themselves they spoke about finding information on diabetes mellitus in pregnancy online and via internet discussion forums. This was especially true if women had already had a previous successful pregnancy. The impact of a previous successful pregnancy was also noted by another study.<sup>37</sup> In this study, women with prior successful experiences described how they thought it was best if they 'just got on with it'. One woman said 'We think we know how to have babies and before we didn't, so . . . last time we sought a lot of advice and this time we've just gone and got on with ourselves'.

Prior successful experiences of pregnancy are clearly relevant to knowledge about PCC. So, too, are experiences of pregnancy loss and/or other complications of diabetes mellitus in pregnancy; five<sup>33,34,37,40,41</sup> of the published studies in this review explored this issue.

In the study by Murphy *et al.*,<sup>37</sup> it was reported that, of the 14 women who had been pregnant before, 12 reported one or more complications ranging from major complications such as miscarriage and stillbirth through to minor complications such as the baby being born with shoulder dystocia. What was particularly interesting about this was that, as the authors argued that ' . . . women did not necessarily attribute these previous complications or poor outcomes to lack of PPC [prepregnancy care] and it did not seem to prompt them to seek PPC for subsequent pregnancies'.

One of the women in the study<sup>37</sup> said that it prompted her to seek PCC in subsequent pregnancies:

*The first time round I had actually had two miscarriages previously, probably that's why I went [for pre-pregnancy care]. Yeah I had a miscarriage after my daughter as well . . . but I didn't, I didn't actually know that I would get pregnant so quick.*

In the study by Richmond,<sup>40</sup> two of the women interviewed who had lost babies in previous pregnancies said that this motivated them to seek PCC:

*I went and got help before I got pregnant because me blood sugars were going up before I got pregnant . . . Me HbA<sub>1c</sub>s have been absolutely fantastic. Me last five have been like 6.1 and 6.0 and I've been jumping for joy!*

*Yeah we decided we would try for another one . . . made sure my blood sugars were good before I started . . .*

Two further studies<sup>33,41</sup> also supported the idea that women with pre-existing diabetes mellitus who have experienced previous pregnancy loss are more likely to be aware of PCC and value its importance. However, this does not mean that they are more likely to attend PCC. McCorry *et al.*<sup>34</sup> argued that the

experience of miscarriage actually prevented one woman from seeking out any type of information on diabetes mellitus in pregnancy. She said:

*I made a conscious decision not to read a huge amount, not to overeducate myself, because I knew that I have a tendency to be anxious, so therefore I thought – no, my job simply is to make sure that my blood sugars are good.*

The literature suggested that previous pregnancy loss may encourage some women to attend PCC but certainly not the majority.

This systematic review indicates that not all women were aware of the existence of PCC services. Even when they were aware, several factors were barriers to attendance; some women considered themselves to be knowledgeable enough whereas others did not think that PCC was relevant. It is also important to bear in mind that women do not necessarily equate pregnancy planning with attendance at PCC.

### **Everyday life, diabetes mellitus and identity**

Of the 18 published papers in this systematic review, 12<sup>28,29,32–35,37,39–43</sup> discussed a range of issues that can be thematically understood as focusing on women's experiences of everyday life, diabetes mellitus and identity. The subthemes contained within this theme include the notion of diabetes mellitus in pregnancy as something that is 'hard work', the desire for normality and control in the context of a high-risk and medicalised experience of pregnancy, and the significance of the family and social support networks in the lives of women who experience diabetes mellitus in pregnancy or pregnancy planning. These three subthemes all have a bearing on the extent to which women might engage with PCC and are discussed in the next three sections.

### **Diabetes mellitus in pregnancy as 'hard work'**

Out of the 12<sup>28,29,32–35,37,39–43</sup> studies that explored everyday life, diabetes mellitus and identity, eight<sup>28,32–35,40,41,43</sup> describe the way that women regarded diabetes mellitus in pregnancy as 'hard work' or something that needed to be worked at.

There is a particular focus within this subtheme on the work required to reduce and maintain acceptable blood glucose levels. Three<sup>32,41,43</sup> out of the 10 studies that explored diabetes mellitus in pregnancy as hard work focused on this issue. For example, one study<sup>41</sup> discussed the requirement for women to test blood samples between four and seven times a day to establish glycaemic levels. The author found that the women in the study regarded this testing to be a 'chore' and 'hard work'. One of the women interviewed talked about the hard work she put in to get her blood glucose levels right 'I worked really hard to get my sugars at an acceptable level' (p. 267).<sup>41</sup>

In another study,<sup>32</sup> women also talked about the 'discipline, stress, and sheer hard work involved' in establishing good glycaemic control. The women interviewed in this study described the lengths to which they had to go in order to achieve this. One woman described how she changed jobs and eventually gave up work before having children in order to accommodate the preparation for pregnancy: 'I decided to give up work before I had children, because of the immense amounts of pressure to try and keep everything controlled and everything so tight'.

Another woman in the same study described how the structure of her life changed completely prior to conception because she lost all recognition of the symptoms of hypoglycaemia. She said 'I could be walking around on 1.5 mmol and then just pass out, my whole life structure pretty much changed'.<sup>32</sup>

Some women talked about how they worked alongside their diabetes mellitus team in order to establish good glycaemic control. One of the interviewees in third study<sup>43</sup> remarked on this: '... because we know the implications of being pregnant in diabetes ... we worked with them for about 18 months ... there was a dramatic change to the HbA<sub>1c</sub> ...'.<sup>43</sup>

In other studies, women talked about the way in which 'real life' got in the way of preparing for pregnancy and managing their diabetes mellitus. This was explored by five studies.<sup>34,35,38,40,41</sup> Richmond<sup>40</sup> for example argued that although achieving optimum glycaemic control is of paramount importance to the health professionals that care for women with diabetes, complying with medical advice often slips down the list of other important 'things to do' for the patients.

All of the participants in this study, each of whom had T1DM, said that looking after themselves was a very time-consuming activity and that monitoring their blood glucose so often left them with little time to do anything else.

Other studies echoed the views expressed by all of the women in Richmond's study.<sup>40</sup> In one study,<sup>34</sup> which also focused on the experiences of women with T1DM, women said that life 'got in the way' of things. The participants in another study<sup>28</sup> (women with pre-gestational diabetes mellitus) said that work and responsibilities for childcare got in the way of recommendations for diet and exercise.

The frequency of health-care appointments for women with diabetes mellitus was also cited as an issue that was problematic in the context of women's lives, particularly as women with diabetes mellitus require more frequent visits in comparison with the general population. In the participatory research project carried out by O'Higgins *et al.*,<sup>38</sup> some women said it would be difficult to make the time to attend PCC because of travel, work and childcare commitments. Some of the comments on this included 'Difficult for some people to take responsibility of time management to get into clinic' and 'Some may find the frequency of appointments as interfering with work/life, etc.'<sup>38</sup>

This was also noted by Lavender *et al.*<sup>33</sup> Writing specifically about women's experiences of pregnancy, the authors argued that women's lives were seriously disrupted by diabetes mellitus and that it would be useful to explain this to women before they become pregnant. One of the women in this study described the stress she experienced:

*I would say it's more stressful because you're more in hospital. You're coming at least twice a week . . . It's too much. And then I think, 'Oh, my God, is this all necessary?' and the waiting times are just a laugh.*

In two<sup>35,41</sup> out of the five<sup>34,35,38,40,41</sup> studies that explored the views of health professionals, there was some evidence to suggest that some practitioners were aware of the hard work and motivation required by women with diabetes mellitus in pregnancy. For example, one of the respondents in the study by Mersereau *et al.*<sup>35</sup> said:

*The whole course of the pregnancy is going to be a lot of work. She's going to be doing her blood sugars a lot more often than she usually does, and her diet is going to have to be under much tighter control.*

Similar views were expressed by practitioners in Shawe's<sup>41</sup> study. She argued that health professionals often recognised the motivation to 'work hard' as one of her participant's commented that 'we worked really hard, and her HbA<sub>1c</sub> is now 6, so she's done really really well, very impressed . . .' (p. 267).<sup>41</sup>

There is relatively little literature on the perspectives of health professionals who support women with diabetes mellitus in pregnancy and pregnancy planning. Only two studies<sup>35,41</sup> indicated that some health professionals may be cognisant of the work put in by women, but it is not clear how widespread this is nor is there evidence to suggest that this acknowledgement is shared with women themselves. In four<sup>34,38,40,43</sup> of the studies that focused on women's views and experiences, women were often critical of health professionals, arguing that they did not appreciate the work it took to manage their diabetes mellitus in pregnancy or in preparation for pregnancy. In the study by Richmond,<sup>40</sup> for example, women expressed a fear of being labelled as 'difficult' by health professionals if they were unable to meet stringent requirements

for blood glucose control. One woman in this study described herself as 'trying really hard' even though she had not been successful in the eyes of her practitioner.<sup>40</sup> In the study by McCorry *et al.*,<sup>34</sup> one woman said that she was 'frustrated' because 'doctors need to be aware that pregnancy for some women is a roller coaster'.<sup>34</sup> O'Higgins *et al.*<sup>38</sup> noted a similar pattern and said that women struggled with diabetes mellitus management and wanted health professionals to acknowledge this. One of the women in their study spoke about this need for acknowledgement: 'Staff don't realize you live a real life and you are not a robot and there will be days with high blood sugars . . . Sometimes we will get it wrong'.

In another study,<sup>43</sup> women also expressed the same view that managing diabetes mellitus in pregnancy was hard work and that health professionals did not acknowledge how difficult it was and the physical and emotional effort that went into it. One of the interviewees in this study said 'It just feels like it's not **quite** realised . . . how hard it can be . . . it's a constant, constant battle, the injecting is **nothing**. It's everything else that goes with it that you have to control **all** the time.' [emphasis in original].

The findings of this review suggest that women consider pregnancy to be hard work and the management of blood glucose as something to be worked at. Many women became frustrated when they felt that health professionals did not acknowledge, or were dismissive of, the work that they put in to manage their diabetes mellitus. The limited literature that exists on the perspectives of health professionals suggests that some professionals are aware of this, but it is not known if and how they communicate this to the women they care for.

### The desire for normality and control

It is not surprising that within the context of what has been described in the literature in the section *Diabetes mellitus in pregnancy as 'hard work'*, the desire for normality and control in the context of such a high-risk and medicalised experience emerges as the second subtheme within the broader theme of 'everyday life, diabetes and identity'. An analysis of the studies within this systematic review indicated that 8<sup>33–35,37,39,40,42,43</sup> out of the 12<sup>28,29,32–35,37,39–43</sup> studies within this broader theme focused specifically on women's desire for a more 'normal' experience out with the need to manage their diabetes mellitus.

In two<sup>33,42</sup> of these studies, women expressed particular concern about not having enough control over pregnancy or their plans for pregnancy. In one study,<sup>33</sup> women (with T1DM and T2DM) who had not previously been pregnant recognised the impact that diabetes mellitus would have on any future pregnancy. They feared being labelled and wanted the focus of their pregnancy to be on their pregnancy itself and not on their diabetes mellitus. One woman in the study said 'It's like you get a label on you isn't it? And they just think, you know, they've got to focus on just that and I feel by focusing on my diabetes . . . it frightens me then and I start panicking about it [pregnancy] . . .'.

In the other study,<sup>42</sup> some women felt that health professionals wanted to control if and when they had children and this meant that they were reluctant to engage with PCC. One woman, who had been pregnant before and was advised not to have more children, said that she had not sought advice from them again: 'I don't want to hear you telling me I can't have more children, so I just went ahead'.

Another woman felt that health professionals wanted to control her pregnancy plans, which she found controlling and restrictive, and said '[i]t's so restrictive . . . they're planning when I'm going to have it, not when I want to have it'.

It is interesting to contrast the voices of women describing how they sought to achieve normality and control within the context of managing a long-term condition with the perceptions of the health-care professionals who care for women with diabetes mellitus. Two studies<sup>35,39</sup> reflected the views of practitioners on this matter and, in particular, reflect a concern with 'patient compliance'. In the first study,<sup>39</sup> the authors argued that a 'majority of physicians considered patient compliance with recommendations and patient follow-up to lifestyle changes to be major concerns . . .'.

This study, conducted in the USA, gathered data on the views of 510 physicians via postal questionnaire. The study aimed to assess the barriers to, and quality of, care received by women with diabetes mellitus from obstetricians and gynaecologists. In the second study,<sup>35</sup> which reported the views of practitioners on the attitudes and barriers to achieving good glycaemic control, concern was also expressed about a lack of compliance and women were described as being 'in denial', not taking responsibility, not being motivated and not being proactive. One of the respondents in the study said 'I think it's just denial . . . Nothing's going to happen to the baby. I'll be OK if I skip a few days of my medication. I'll be OK if I don't check my sugars regularly, you know?'.

Although every woman will want to have a good pregnancy and a healthy baby, the review of the literature suggests that there is also an overwhelming desire to normalise pregnancy and to experience some of the excitement and joy of planning pregnancy, being pregnant and having a baby.

Some women just wanted their lives to be as normal as possible, in spite of having diabetes mellitus. Two of the women in the study carried out by Murphy *et al.*<sup>37</sup> highlighted this view. The desire for a normal experience of pregnancy and pregnancy planning is cited by both as the reason why they would not attend for PCC. One of the women in this study said 'It was a lot to do with the relationship I was in as well, sort of like breaking up with him and I was . . . "I can't be bothered any more to do that" '.

The concept of enjoyment expressed by the quotation above can be found elsewhere in this systematic review. In another study,<sup>34</sup> women reported that information they had received about the risks of pregnancy with diabetes mellitus had made them anxious and prevented them from accessing PCC. One of the women in this study spoke about the lack of joy in this: 'For my first 3 months of being pregnant, I had no joy in it, no joy. I just kept fretting . . . and for a good part of it I didn't tell anybody'.

Indeed, many women spoke about not just wanting a normal experience but wanting to feel the 'joy' of preparing for pregnancy. For example, Lavender *et al.*<sup>33</sup> proposed that health professionals should seek to normalise the experience of pregnancy for women to ensure that women had a positive experience, balancing 'the need for safety with that of enjoyment'.<sup>33</sup> The study by Woolley *et al.*<sup>43</sup> reinforced this view. The respondents in their study spoke about wanting the focus to be on the 'fun aspects' of pregnancy, rather than on the medical management of their diabetes mellitus. When asked what was important to her, one woman said:

*The **fun** aspects I suppose of being pregnant. Yes I'm diabetic, **but** I'm also just a normal person having their first experience of pregnancy. And I don't know how to change a nappy or breast-feed just like everyone else . . . [emphasis in original].*

The participants in Richmond's<sup>40</sup> study also talked about not being able to enjoy pregnancy. Two of the women in the study, who had been pregnant, previously talked about being 'robbed of enjoyment' and expressed feelings of anger and resentment towards their diabetes mellitus:

*I think you feel anger more towards your condition more than the pregnancy, because you think well why can't I just have a normal pregnancy like anyone else?*

*I don't think diabetes and pregnancy goes at all, so there should be a massive ban on diabetics ever getting pregnant at the moment . . . because it's like having about eight children . . . and you just can't enjoy being pregnant.*

Many of the studies in this review have highlighted that women with pre-existing diabetes mellitus are concerned about being able to control their experiences of pregnancy and pregnancy planning. Within the context of living highly medicalised lives, women seek to normalise their experiences of having a baby, wanting to experience the anticipation, joy and excitement that they see as part of a 'normal' experience. This desire for normality may impact on PCC when this is seen to negatively affect that desire.

## The role of family and social support

The literature reviewed indicates that women's experiences of pregnancy planning cannot be fully understood without placing them within a wider social context. The significance of family and social support networks in the everyday lives of women who experience diabetes mellitus in pregnancy or pregnancy planning is discussed in 6<sup>28,29,33,35,37,41</sup> studies out of the 12<sup>28,29,32–35,37,39–43</sup> within this theme.

As discussed in *The complexities of pregnancy planning*, women's pregnancy planning behaviour can be influenced by the views of family, community and culture. In particular, the literature showed that women's contraceptive use can be influenced by the wishes of husbands and partners.<sup>41</sup> However, the views of friends and family have a more penetrating influence on women with pre-existing diabetes mellitus before, during and after a pregnancy. An appreciation of this can be seen in the literature focusing on the views of health professionals. One practitioner included in the study by Mersereau *et al.*<sup>35</sup> noted the influence of the husband and wider family on diabetes mellitus in pregnancy: 'It's really interesting, the cultural things going on sometimes. In what he [the husband] perceives to be good for the pregnancy or what the patient's mother-in-law thinks should go on for their future grandchild'.

In Devido's<sup>29</sup> study there was also recognition of the role of the partner and wider family in supporting women. This study examined the experiences of 48 parish nurses in providing diabetes mellitus education and preconception counselling to women with T1DM or T2DM. Here, parish nurses appreciated that it could be difficult for women to follow lifestyle recommendations and that having 'everybody on board' to help could be really advantageous for them. Writing specifically about the experiences of South-East Asian women, Lavender *et al.*<sup>33</sup> concurred with this viewpoint, arguing that family and friends were the greatest influence on this particular group of women. They discussed the case of one parous woman who was 'not allowed to breastfeed' because her mother thought this would put the baby at risk of diabetes mellitus. Lavender *et al.*<sup>33</sup> concluded that it would be useful if health professionals engaged more with significant family members, when appropriate.

An analysis of the published studies shows that, in some instances, women wanted more social support than they currently had. For example, one study<sup>28</sup> reported that black women especially value social support from family and friends, but that this is not always in place. One woman in this study felt that it would be easier to be healthier with more social support. She said 'I think having a support system in every aspect of your life, at home and work [would make having a healthy pregnancy easier]'.

The authors argued that a lack of social support is a significant barrier to the care of women with pre-existing diabetes mellitus.

In the study by O'Higgins *et al.*,<sup>38</sup> the women who participated in the focus group discussions expressed the view that women's social support networks were invaluable in supporting women to maintain a healthy lifestyle. They also felt that the involvement of significant others in women's care could be useful and would enable women to receive ongoing understanding and support, as well as informed opinions. Shawe<sup>41</sup> also commented on this need, specifically in relation to the management of hypoglycaemic episodes. As discussed in *Knowledge of pregnancy planning, diabetes mellitus and risk*, the literature suggests that the management of hypoglycaemia causes women considerable difficulties. Shawe<sup>41</sup> suggested that partners, friends and family can have a significant role in managing hypoglycaemia in order to support women and to deliver glucagon treatment if necessary.

Although some women were pleased to receive social support and had good networks, others found the influence of family and friends to be unhelpful. For example, the literature suggested that women with pre-existing diabetes mellitus could sometimes feel additional pressure from family and friends in relation to the decision to have children and when trying to conceive.<sup>33</sup> Sometimes women also felt 'nagged' by their family. This was also reported by Shawe,<sup>41</sup> who described how this 'nagging' could sometimes make women feel resentful and rebellious.



Shawe<sup>41</sup> described how women felt resentful and that it made them feel 'rebellious'. One woman described just wanting 'to be left alone'.

The literature review showed that whether women receive too little social support or were well networked within a circle of friends, family and community, and regardless of whether they saw the support they received as helpful or not, the role of partners, family and wider social networks were an important part of women's everyday lives.

### Meeting women's needs

The three themes already discussed above have focused on women's beliefs, their knowledge and their experiences of everyday life with diabetes mellitus. In the final part of this systematic review, the focus shifts to the way in which health-care providers can best focus, deliver and organise PCC in order to meet women's needs. Three subthemes have emerged from the analysis of the data: (1) effective communication and relationships, (2) the provision of individualised care and (3) the co-ordination and organisation of care. All of the studies included in the review discuss one or more of these subthemes.

### Effective communication and relationships

Twelve<sup>26,28-33,35,37,38,40-43</sup> of the studies in the systematic review focused on the topic of communication and relationships between women and their health-care providers. The studies focused both on the consequences of poor communication on how women came to feel about seeking advice and on the benefits of good communication and relationships, and the impact this can have on the uptake of PCC.

Six<sup>32,33,38,41-43</sup> of the studies suggested that health-care practitioners can adopt communication styles that are perceived by women to be authoritarian and paternalistic. The authors argued that this can make women feel 'nagged', judged, intimidated and afraid of being 'lectured'. In one study,<sup>33</sup> which explored the experiences of white British and South-East Asian women with T1DM or T2DM, one woman recalled a previous experience of attending a preconception clinic:

*I found it really intimidating just because it was . . . the way that it was kind of drummed in, 'You can't get pregnant until your blood sugars right!' kind of thing and it were like, 'Yeah, fine' but who are you to kind of judge me on that.*

Very similar findings can be found in the study by King and Wellard.<sup>32</sup> In this study, which explored the experiences of seven women with T1DM living in rural Australia, respondents said they often had to deal with health professionals who were very authoritarian in their approach. Women said that this approach was undermining and sometimes made them fearful. One woman said she was told ' . . . just don't get pregnant now because if something happens to the baby you will never forgive yourself'.

Another woman described being bullied by her obstetrician:

*With my first obstetrician, my pregnancy was made into a side show . . . he went completely overboard . . . I would be doing 13 tests a day and if I missed one. He'd have me in tears, [saying] don't you care about this child.*

In contrast, the women in this study said they were satisfied with their care when they felt treated like 'adults'. In these instances, they felt supported and more confident in the management of their blood glucose. Given the rural setting, interactions were not always conducted face to face but sometimes by e-mail and telephone calls, and these methods worked well. According to one study, nulliparous women, in particular, are most likely to feel judged and intimidated by health professionals.<sup>42</sup>

Shawe<sup>41</sup> suggested that communicating in a style that was authoritarian and paternalistic is a form of social control. One assumes that such a style is intended to be informative and to encourage positive behaviour change. However, Shawe<sup>41</sup> argued that, for some of the women in her study, the opposite was

true because it made women far less receptive to advice or care. Although most of the published studies that discussed this issue would concur with Shawe, two studies do not support these findings.<sup>38,43</sup> In fact, Woolley *et al.*<sup>43</sup> argued that that women in their study thought that ‘scaring women’ could actually encourage women to attend PCC.

Several of the studies reviewed conclude that better communication is an important aspect of improving care for women with pre-existing diabetes mellitus,<sup>28,31,37</sup> but that health professionals are often seen by women to be unsupportive of their needs.<sup>42</sup> Holing *et al.*<sup>31</sup> argued that the way in which practitioners deliver information to women is ‘crucial’ to the delivery of effective health care. In addition, Murphy *et al.*<sup>37</sup> suggested that health professionals involved in the care of women with diabetes mellitus need advanced communication training.

In addition to highlighting the importance of authoritarian and paternalistic approaches on women’s receptivity to PCC and advice, the focus of the advice that women had received previously was also a significant aspect of the findings in seven of the reviewed studies.<sup>28–30,32,35,37,41</sup> These studies highlighted that practitioners often focus on the risks and possible negative outcomes of diabetes mellitus in pregnancy rather than on the opportunities for positive change.

Women with T1DM diagnosed in childhood or adolescence often recalled being told that they should not, or cannot, have children. For many women this is a devastating blow, leading to fear and anxiety later in life. Several of the women in the study by King and Wellard<sup>32</sup> expressed this view and the fear that they felt. One woman described what she was told when she was diagnosed as a child:

*As a child when I was diagnosed, at that time, I was told that I may never have children and that if I was to have children that perhaps the last 3 months of pregnancy would be spent in Melbourne [major city], in bed and restricted and things like that, so having children was always a scary, scary thing for me.*

A very similar picture is found in the findings presented by Shawe,<sup>41</sup> Griffiths *et al.*<sup>30</sup> and Spence *et al.*<sup>42</sup>

More generally, the literature suggests that the focus of information and advice given to women with diabetes mellitus is quite negative and that this negativity does not benefit the relationship between woman and health-care provider, nor the likelihood that women will be receptive to PCC. Negative messages received during attendance at PCC also contributed to women’s anxieties. In the study by Griffiths *et al.*,<sup>30</sup> three women talked specifically about how fearful they felt after attending preconception counselling. Instead of the experience being informative and supportive, women became upset and unsure about what to do. One woman said:

*We’d gone to the hospital and we’d had prepregnancy counselling . . . which wasn’t very positive . . . it was a very, very negative experience . . . We were filled with dread really about the consequences of getting pregnant – for me and for the baby . . .*

Another woman, this time reported in the study by Murphy *et al.*,<sup>37</sup> also recounted the negative impact that PCC could have on women’s experiences:

*Well, now as soon as you mention the P-word [pregnant] they’re gonna come down on me like a truck. ‘Oh you shouldn’t be havin it.’ And that’s gonna make you feel even worse in the first place . . .*

In the study by Collier *et al.*<sup>28</sup> – a US study that reported on the experiences of black, white and Spanish women – women commented specifically on how much more receptive they were to care and advice when health-care practitioners could focus on the positive aspects. One woman in their study wanted to know about the positive effects of glycaemic control. She said ‘There was just all kinds of negative stuff,



and sometimes you don't want that doctor to just put it out there like that . . . Tell me. but give me something positive also'.

What is interesting about this is a desire for information that is positive and balanced. In the study by Mersereau *et al.*,<sup>35</sup> one of the five studies<sup>29,35,36,39,41</sup> that reported on the views of health professionals, practitioners commented on how they talked to all of their patients mostly about complications and risks to the baby. However, Devido,<sup>29</sup> who also focused on the perspectives of practitioners, said that what is required is 'A more positivistic approach . . . rather than consequence related' (p. 76).<sup>29</sup>

In summary, the published studies indicate that women's needs for PCC are best met when health-care providers are able to communicate effectively with the women in their care. However, communication was often perceived as authoritarian and paternalistic, and women sometimes felt judged, guilty, scared and pressurised rather than empowered and supported. This review suggests that advice often focused on messages about negative outcomes rather than on the positive changes that women might make when planning a pregnancy. Focusing on the latter might encourage some women to engage more with the support being offered by health-care professionals.

### The provision of individualised care

The findings of this review suggest that when women receive advice and care they want to be acknowledged as a person first. In other words, they want to be recognised as a whole person who is neither 'just' a diabetic patient, nor a pregnant woman, but as someone who has individual needs, a life history, aspirations and goals for the future, and a 'real life'. Half of the studies included in this systematic review explored the importance of providing individualised care as a means of improving women's receptivity to pregnancy planning.

The review of the literature suggested that advice on pregnancy planning is not always delivered in a timely way. It suggested that advice could be offered routinely or opportunistically but without focusing on women's particular needs. Richmond,<sup>40</sup> in her study of 11 women with T1DM, argued that women could receive constant medical attention that came across as repetitive, rather than informative. In the study by Murphy *et al.*,<sup>37</sup> which specifically focuses on the views of women who did not attend PCC, several women described how they were less receptive to PCC because they had been offered information and advice at times that were not relevant to them. Some of the women said:

*I've always been told ever since I was about fifteen or sixteen attending clinics how important it is . . . I always used to laugh, you know, and say, I'm only sixteen, I'm not going to have a baby and . . .*

*I mean we weren't really thinking about it at that time so I mean it was all like pushed to one side. Yeah, so I probably wouldn't have taken much notice about it if they would have said anything.*

*It's not that the doctor was kinda skimming over it; it was always me kinda wanting to hurry that part along<sup>4</sup>*

*If you're coming up here every 3 or 6 months; if every time you come in you've been told, 'And if you're planning a pregnancy don't forget to make us aware', I think that you'd get a bit sick of it to be fair.*

In another study,<sup>34</sup> approximately one-third of research participants said that they just 'filtered out' information about pregnancy because it was not important in their lives. One woman, who had attended a dose adjustment for normal eating course, said that she just 'tuned out' when anything about pregnancy planning was mentioned.

Constant advice that is repetitive and untimely can actually be a disincentive to women in accessing PCC, although one study dissented from this perspective.<sup>27</sup> In this study some women were generally very

receptive to discussions about pregnancy planning even if they had not brought the topic up themselves. For some women this was preferable because they found it hard to raise the issue.

In the study by Power *et al.*,<sup>39</sup> all of the doctors said that most times, if not every time, they discussed pregnancy planning with women, they did so regardless of whether or not the woman was planning to have a baby. In contrast, some of the practitioner respondents in Shawe's<sup>41</sup> study described how they tried to adopt a more personalised approach to how they provided PCC.

Of course, although this approach might seek to acknowledge the individual circumstances of the woman concerned, other literature warns against an approach based on stereotypes and preconceived ideas about when it is the 'right' time to have a baby (see *The complexities of pregnancy planning* for a discussion of this). However, not all of the practitioners in Shawe's study<sup>41</sup> took this approach. One of the diabetes mellitus specialist nurses who was interviewed acknowledged that advice on pregnancy planning was relevant only 'when it was relevant' and that sometimes women found it hard to discuss this.

The literature reviewed suggests that women prefer care that is focused on them as individuals. This means focusing on them as a whole person and not just on the health of their fetus or future baby or on their diabetes mellitus care. This view was expressed in one study,<sup>26</sup> in which one participant said:

*And then that's how it felt, is it just because I'm carrying a baby, because otherwise they don't care, or they don't care about me. And that's how it is, isn't it? And it's very, like, here you are, you're pregnant and we're focusing on the baby.*

Although concern for the fetus is entirely understandable, a lack of focus on the whole person meant that this woman felt that nobody cared about her. In other studies, authors report that women complain when the focus is on diabetes mellitus rather than on the experience of pregnancy.<sup>33,43</sup>

Providing care that is based on individual need means that health professionals must have an understanding of an individual's history and goals. Several studies focused on this and discussed the importance of the relationship between the woman and her practitioner and/or the importance of continuity of care. In the study by Spence *et al.*,<sup>42</sup> the authors suggested that women preferred someone who was 'approachable' and who understood their 'real life'. The study included women with T1DM and T2DM but older nulliparous women in particular commented on the difficulty of establishing a relationship with their diabetes mellitus team because of a lack of continuity in care. This was important because it prevented them from being able to ask advice about planning a pregnancy. One woman in this study said '... I don't get the same person, so I could never have that conversation'.<sup>42</sup>

The importance of continuity of care was also a finding in two other studies.<sup>34,43</sup> In both studies, women expressed irritation and frustration with health professionals who did not know them or provided care that was not individualised. For example, one woman in the study by Woolley *et al.*<sup>43</sup> described the irritation of having to repeat herself:

*Telling my story . . . I think was a big thing. Every time I met a new professional I had to explain. An' it irritated me after a while, 'cos I thought 'Read the notes before you walk into the room to see me'.*

A woman in the study by McCorry *et al.*<sup>34</sup> expressed her irritation when her individual needs and goals were not known:

*I go and speak to my doctor, and the doctor says to me, 'Well, it's important you get your bloods done [if planning a pregnancy].' Well, I knew that already. What was the point in me going to the doctor?*

There is a certain view that advice on PCC should be provided to every woman of childbearing age frequently, either routinely and/or opportunistically, but if it is not timely the literature suggests that women are unlikely to be receptive. Furthermore, providing advice routinely and/or based on preconceived ideas that a woman might be thinking about pregnancy can be off-putting. This systematic review shows that women are generally more likely to be receptive to PCC when advice is tailored according to individual need by health professionals who have a personal relationship with each woman and understand her life history and goals for the future.

### The co-ordination, organisation and delivery of care

In focusing on the issue of meeting women's needs, 13 of the studies in this systematic review have highlighted concerns with the way in which PCC is co-ordinated and delivered.<sup>27,29,30,32,33,36-43</sup> In particular, there appears to be a lack of clarity as to who is responsible for the delivery of PCC and considerable discussion about which practitioner is best placed to provide it. Many of the studies, particularly those that focused more explicitly on the barriers to, and facilitators of, the uptake of PCC, or on its delivery, also discussed practical suggestions on how PCC services could be improved. Some studies also focused on the need for increased contraception counselling.

The literature reviewed raises questions as to who is responsible for the provision of PCC with the multidisciplinary team of health professionals who deliver care to women with diabetes mellitus. On analysing the data presented within the various studies, it is particularly helpful to explore the issues from the perspectives of practitioners working in either secondary or primary care as this seems to be where the issues lie. The study by Mortagy *et al.*<sup>36</sup> is particularly relevant because it sets out to explore the perspectives of GPs and secondary care health professionals on the role of the GP in delivering PCC to women with diabetes mellitus. Many of the seven members of the secondary health-care team who were interviewed raised concerns about the role of the GP and the quality of service provided. Hospital team members argued that GPs were crucial members of the multidisciplinary professional team but that they were missing. One diabetes mellitus specialist nurse highlighted the critical nature of the GP role, especially in relation to identifying women with T2DM. Some members of the secondary care team thought that GPs did an excellent job and actually wanted to see more PCC being taken on by GPs in their area, especially as this meant that women could be seen 'closer to home'. However, others were sceptical about the quality of service provided. One hospital consultant said '... there are some GPs who have no interest at all and their general level of diabetes care is very poor'.<sup>36</sup>

One particular issue seems to be a lack of referrals from GPs to specialist hospital clinics. A hospital consultant spoke about this issue and compared referrals from the assisted conception unit with referrals from GPs: 'Well, I think they're [assisted conception unit in hospital] very good, because I get some referrals from them, whereas, I don't get any GP referrals for preconception care. I cannot remember if we have ever had one'.<sup>36</sup>

The health professionals interviewed in the study by Shawe<sup>41</sup> also expressed concern about a lack of referrals and the lateness of referrals when they did occur.

Even though secondary care health professionals value the role of the GP in the provision of PCC, they are mostly critical of the care provided considering it to be either missing or poor quality. However, the authors of this study also interviewed eight GPs.<sup>36</sup> It is interesting to note that although hospital team members thought that GPs could play a valuable role, most GPs thought that the problem of low uptake of PCC was only a problem that affected a 'minority of minorities'. Moreover, T2DM was seen to be a 'disease of the elderly' rather than something that might affect women of childbearing age. These views may well have a bearing on the services GPs provide and the emphasis they place on providing PCC or referring women on. As might be expected, there was a contrast in perspective between GPs with a special interest

in diabetes mellitus and those without. One diabetes mellitus lead in the study by Mortagy *et al.*<sup>36</sup> described him/herself as highly involved and said:

*If they were young and fertile, I'd make sure their drugs were . . . safer if they got pregnant and I would get their control as good as it was and I'd emphasise they must come and see us as soon as they're pregnant.*

In contrast, the authors point out that GPs without a special interest in diabetes mellitus talked quite vaguely about PCC. One GP said he or she had 'never really thought about this topic before . . .'.<sup>36</sup>

In relation to the topic of making referrals the division of responsibility between primary and secondary care seemed quite blurred for GPs and, as the authors argue, a source of tension. In one account given it is clear that this blurring of responsibilities leads to missed opportunities for care. One GP diabetes mellitus lead in the study by Mortagy *et al.*<sup>36</sup> said:

*Although we tried to engage her [the patient] here as well as her seeing the hospital . . . we then didn't make her come in and see us. So, because we weren't doing the organised care, we won't have gone through the template . . .*

The GPs in this study thought that PCC should be a joint responsibility between primary and secondary care. Both GPs and secondary care health professionals believed that a lack of clear guidelines on how to provide PCC and when to make referrals was responsible for the blurring of boundaries and source of tension.

There was also some limited discussion about a lack of liaison with fertility services, but this was mentioned only in the study by Shawe.<sup>41</sup> The concern here was that some women who became pregnant after undergoing fertility treatment may not be simultaneously planning for pregnancy in relation to the management of their diabetes mellitus.

Shawe<sup>41</sup> and Murphy *et al.*<sup>37</sup> discussed the provision of pregnancy planning and contraceptive services and their data indicated that another gap in service provision might exist. The participants in Shawe's study<sup>41</sup> who worked within a secondary care health team believed that having conversations about contraception was not really their role.

The data presented indicate that some practitioners do not see themselves as qualified to provide contraceptive advice, preferring to refer women either to a family planning clinic or back to their GP.

Murphy *et al.*<sup>37</sup> also highlighted the significance of contraceptive services in relation to the role of PCC, arguing that they are particularly relevant to younger women for whom a future pregnancy will seem a long way off. But, the authors argued that better integration between diabetes mellitus care and reproductive health-care services is needed across both primary and secondary care, warning that failure to provide co-ordinated care will have 'devastating consequences' for women.

All of the studies that commented on the role of the health professionals in the delivery of PCC concluded that more information, advice and training was needed. For example, in Shawe's 2008<sup>41</sup> research, health professionals viewed pregnancy in diabetes mellitus as quite a specialist area of work, saying that there was little training or education available specifically in relation to the provision of PCC. All of the GPs interviewed in the study by Mortagy *et al.*<sup>36</sup> thought that further training and support for them was needed. Another study identified that further training on diabetes mellitus in pregnancy was needed for midwives.<sup>32</sup>

Many of the studies reviewed commented on how PCC is currently delivered and how it might be delivered in a more effective way at a practical level. Many suggestions were given and one common suggestion was to use peer support as a means of educating women about diabetes mellitus and as a way of providing

support to for women more generally.<sup>29,38,40–42</sup> In one study,<sup>38</sup> all of the women involved in focus group discussions felt that peer support could be a powerful tool. Ideas for peer support included coffee mornings and support groups. Richmond<sup>40</sup> noted the value of support groups, including postnatal support groups that brought together women at different stages of pregnancy and pregnancy planning. Ideas such as this were also discussed by the health-care professionals in Shawe's study.<sup>41</sup> One practitioner spoke about having set up 'girly nights' but admitted that these nights had not worked because attendance had been very disappointing. When asked about peer support, the women who participated in the study by Spence *et al.*<sup>42</sup> responded positively to the suggestion and said that it would be 'nice chatting and getting more information from friends who have diabetes'.

The use of technology such as apps and interactive online resources was also suggested. For example, in one study,<sup>38</sup> participants suggested setting up a Facebook (Facebook, Inc., Menlo Park, CA, USA) page or using blogs and forums. This was an interesting suggestion given that many women are already turning to the internet for advice and information on diabetes mellitus in pregnancy. Of the 15 published studies that addressed the views and perspectives of women, 10 demonstrated that women use the internet as a source of information when planning a pregnancy.<sup>27,28,30,32,34,35,38,41–43</sup>

One of the women in the study by King and Wellard<sup>32</sup> said:

*... there definitely needs to be more information out there ... I was really surprised at first because there was just nothing there ... My basic support was a website based in America that was for diabetic pregnant mothers and type 1 diabetics and it was a sole lifeline.*

Some studies (e.g. Shawe<sup>41</sup>) also suggested that women might prefer discussing PCC with female health professionals. In another study,<sup>42</sup> the authors also argued that some women, especially older nulliparous women, may have a preference for a female doctor or nurse. One of their research participants said 'They should have a dedicated female doctor that you could go for pre-pregnancy advice ... I know the doctor I see is very nice and all, but sometimes he can't even be bothered lifting his head to look at me'.<sup>42</sup>

In brief, a central finding of the included studies was that there is a lack of clarity in how PCC was delivered. It is not clear who is responsible for PCC or who might be best placed to deliver it, and this lack of clarity can lead to gaps in service provision. The place of pregnancy planning and contraception is also in question as is the integration of fertility services. The published research also indicated that many health professionals required further information and training on PCC so that they might provide a better service to women.

## Summary

The narrative synthesis of the 18<sup>26–43</sup> included studies in this systematic review shows that four inter-related themes are significant in relation to experiences and views of PCC. First, pregnancy planning is shown to be a complex phenomenon that can have an impact on the uptake of PCC. Most notable here is the relationship between the social significance of pregnancy for women, the role of fertility beliefs and the problem of categorising pregnancies as 'planned' or 'unplanned', which are categories that often do not resonate with women themselves. Second, women's knowledge and understanding of pregnancy, diabetes mellitus and risk is also significant in terms of a woman's preparation for pregnancy and their likely uptake of PCC. Knowledge about both contraception and the risk factors associated with diabetes mellitus in pregnancy is important. So, too, is knowledge and understanding of PCC itself. Third, the review highlighted how women wanted recognition from health-care professionals for the difficulties they faced in managing diabetes mellitus and diabetes mellitus in pregnancy and the impact that this had on their lives and on their preparation for pregnancy. Women's desire for less medicalisation, more normality and more control was highlighted, as was the significance of family and friends within their lives. Lastly, the significance of meetings women's needs in relation to the organisation and delivery of PCC is also highlighted. Of particular note is the importance of

effective relationships between women and health professionals, the desire for individualised care and the importance of having clear pathways of care for PCC.

Based on this systematic review, the implications for practice are as follows:

- Understanding the complexities of pregnancy planning.
  - Enhanced critical understanding by all health professionals of the misnomer of 'planned' pregnancy and an understanding of the ambiguity and ambivalence surrounding pregnancy intention.
  - Health professionals should have a greater awareness of lay understandings of pregnancy and fertility issues and the impact these can have on PCC.
- Supporting women's knowledge of pregnancy planning, diabetes mellitus and risk.
  - Up-to-date guidance should be available for all women with pre-existing diabetes mellitus of childbearing age concerning the impact of diabetes mellitus on contraceptive choices and the impact of diabetes mellitus medication on fertility and contraception.
  - When giving information to women about diabetes mellitus in pregnancy, women's anxieties concerning their own well-being, concerns for their unborn child or future baby and concerns for existing children should be acknowledged.
  - Given the different ways that women access information combined with the challenges of providing the right information in a timely way, more consideration should be given to alternative means of providing PCC other than through face-to-face consultation.
- Understanding women's everyday lives and needs.
  - All health professionals should acknowledge to women that diabetes mellitus is disruptive to women's lives and that managing diabetes mellitus in pregnancy is hard work.
  - Provision of PCC for women with pre-existing diabetes mellitus should seek to normalise the experience as much as possible and focus on positive outcomes.
  - PCC provision should recognise the importance of family and social support in women's lives and should seek to provide information and support to women's wider circle.
- Meeting women's needs more effectively.
  - Further training on communication to support positive behaviour change and to avoid approaches that are paternalistic and authoritarian.
  - Clear referral pathways for PCC for women with pre-existing diabetes mellitus of childbearing age.
  - Further awareness training for the multidisciplinary health-care team to highlight the importance of diabetes mellitus in pregnancy and the significance of diabetes mellitus for women of childbearing age.





## Chapter 4 Study design and method of the qualitative interviews

The project aimed, through qualitative work, to identify views on the provision of, facilitators of and barriers to the uptake of PCC by:

1. exploring women's views on planned/unplanned pregnancy and the relationship between this and uptake of PCC
2. discussing women's knowledge, perceptions and experiences of PCC, to include women with T1DM or T2DM who have accessed PCC in a range of settings and those that have not
3. collecting the views of staff and other stakeholders on the provision and delivery of PCC, including an analysis of how this care is provided currently and how uptake might be improved
4. making recommendations on how uptake and outcomes might be optimised for all women with diabetes mellitus of childbearing age.

This section of the report outlines the processes for ethics and research and development (R&D) approvals, the role of patient and public involvement in the project, recruitment and interviewing and methods of data analysis.

### Ethics and research and development approvals

At the beginning of the study, ethics approval was gained through the Open University Human Research and Ethics Committee (HREC) and the South Central – Berkshire National Research Ethics Service (NRES) Committee (reference 15/SC/0026). A favourable ethics opinion was granted by the NRES Committee on 5 March 2015 (see *Appendix 4* for the letter showing a favourable ethics opinion). NHS R&D approval was gained from the lead site, the Heart of England NHS Trust, in July 2015.

Data were stored in accordance with The Open University Code of Practice and in keeping with the requirements of The Open University HREC and in accordance with the Data Protection Act. The project is registered with The Open University Data Protection Co-ordinator.

### Patient and public involvement

Service users were involved in the design of the study via participation in two focus groups which included parous white British and South-East Asian women with T1DM or T2DM. One service user (a South-East Asian woman) was a member of the study steering group and involved in the ethics application and the design of all of the patient information forms and consent forms. Lay readers have been involved in critically reading the final project report and the plain English summary.

### Recruitment and interviewing

Only women of childbearing age and with pre-existing diabetes mellitus were eligible for inclusion in the study. The inclusion and exclusion criteria for the study are detailed in *Box 3*.

Recruitment was from a purposive sample in 11 primary care and two secondary care sites. All of the primary care sites were contacted by the research associate (AT) over a period of 4 months (from April to August 2015) with the support of the local Primary Care Research Network. These sites had a total registered patient population ranging from 2644 to 11,370. Primary care managers/administrators



**BOX 3** Inclusion/exclusion criteria for the inclusion of research participants**Inclusion**

Nulli-, primi- and multiparous women with pre-existing diabetes mellitus of childbearing age who have accessed PCC in the past 3 years and those who have not.

Staff who provide PCC and other stakeholders (GPs, nurses, midwives, specialist nurses, diabetes mellitus consultants, community pharmacists and obstetricians).

Women aged  $\geq 18$  years but  $\leq 45$  years of age.

White British women.

Pakistani women whose preferred language is Urdu.

**Exclusion**

Women with diagnosed mental health issues.

Women aged  $< 18$  years or  $> 45$  years.

searched their patient database or diabetes mellitus register, strictly following the inclusion/exclusion criteria and listed the eligible participants for the study. Letters of invitation to participate and participant information sheets were sent either by the site co-ordinator or by the research associate (see *Appendices 5* and *6*, respectively). In total, 50 letters of invitation to participate were sent to 26 potential white British participants and 24 potential Pakistani participants; the latter were sent information in both English and Urdu (see *Appendix 7*). A reply slip and prepaid envelope addressed to the research associate were provided. Five women responded, of whom two were successfully recruited and interviewed: one white British woman and one Pakistani woman. Recruitment in primary care was extremely challenging within the time constraints of the project and significantly less successful than originally hoped for. Additional measures were put into place including widening the study to other Clinical Commissioning Groups (CCGs) and inviting and initiating more GP practices. Attempts were also made to arrange for face-to-face on-site recruitment but appropriate clinics could not be identified.

On-site face-to-face recruitment occurred in secondary care. The research associate (AT) attended PCC and antenatal clinics at both the sites. The sample size population across these clinics was approximately 1800 patients. This method of recruitment to the project was far more successful than sending letters of invitation to participate. From the women with whom the researcher engaged, 10 were successfully recruited and interviewed at a convenient date: eight white British women and two Pakistani women. Another five women wanted to participate, but one was on medication for depression and, therefore, did not meet the criteria, two were unsure and the partner of one participant did not want her to participate. The final participant could not be traced after the initial face-to-face recruitment meeting at the site.

A topic guide was used which addressed a range of issues including pregnancy planning, contraceptive use, experiences and views of PCC, the impact of diabetes mellitus, views on service provision and so on (see *Appendix 8*). As Miller and Glassner<sup>45</sup> note, 'information about social worlds is achievable through in-depth interviewing' (p. 100). A guided interview allows the researcher to probe and understand the meanings people give to their own experiences. The guided interview method also allowed the findings from the systematic review of the descriptive literature to inform the data collection process. Most

participants chose to be interviewed at home, except one who was interviewed at one of the secondary care sites. Signed consent was obtained (see *Appendices 9 and 10* for consent forms in English and Urdu). The interviews took between 30 and 80 minutes, but most were just over 30 minutes. With the permission of respondents, all interviews were digitally recorded and transcribed verbatim by AT – with those in Urdu (of which there were three, one of which was a mixture of Urdu and English) being translated into English by AT, who is fluent in Urdu. At the end of the interview, all of the women were offered an information sheet (see *Appendix 11*) on diabetes mellitus in pregnancy and PCC. This information was also explained verbally to the women who speak Urdu.

Recruitment of staff and stakeholders did not take place because the study closed earlier than anticipated.

## Data analysis

The qualitative interview data were analysed using thematic analysis as broadly proposed by Braun and Clarke<sup>46</sup> and using the method of 'constant comparison',<sup>44</sup> as described in *Chapter 2, Data analysis*.

The transcripts were read and reread by members of the team (CK and SE) and provisional codes and categories shared. CK saved the transcripts as sources in the NVivo qualitative data analysis software package. Interviews were then coded into nodes using NVivo, with 48 distinct codes created. Next, the interviews were reread and the codes agreed between SE and CK. Once this iterative process had been completed, the codes were collapsed into (eight) categories and, from these, themes were developed. From this thematic analysis approach, key issues/themes emerged and partly answered the original research questions as reported below. A 'factual' profile of each participant was written to capture some of the complexity of individual cases – such as the complex obstetric history for some multiparous women. They were also written to help with the development of vignettes to be used in wider dissemination. Despite the limitations of the data set size, it remains feasible to produce vignettes that distil the experience of PCC. The data reported here have been anonymised at source to ensure individual participants cannot be identified.

Commensurate with similar approaches in other qualitative research – and unlike the approach taken in quantitative studies – this project seeks to make conceptual and theoretical generalisations about women's experiences and views of PCC.<sup>47</sup> Although this study included a relatively small population, variables remain important to note insofar as some of them, such as ethnicity, type of diabetes mellitus, educational attainment and obstetric history, have the potential to mark significant differences in the experience of preconceptual care for the population in the study. Therefore, data were coded according to demographic profile classification nodes.



## Chapter 5 Results of the analysis of the qualitative interviews

The data in this study reveal two prominent aspects that relate to the NICE *Diabetes in Pregnancy (Quality Standard)*<sup>48</sup> in that all women who attended PCCs were aware of the need to manage blood glucose levels prior to conception and the majority were aware of the need to take folic acid, even though there were some concerns expressed about when this was started, especially in unplanned pregnancies. When asked about 'lifestyle' choices, women talked about changes they might have made or needed to be made but this seemed to pose difficult dilemmas for some who disclosed levels of personal 'failure' in this respect. For pregnant women and those who had children, the focus at interview was more likely to be on their current and previous pregnancy, or pregnancies, and birth, suggesting a tension between planning for the future and living in the here and now; in other words, short-term concerns overshadowed long-term ones. This section of the report is structured around the themes that have been developed from the data analysis and include pregnancy choices and contraception, enablers to preconception care, barriers to preconception care and the quality of communication with professional carers.

Because of considerable difficulties with recruitment, especially in primary care, only 12 out of the 48 proposed interviews with participants were conducted. The total target number of intended participants recruited to the study for interview was 48, which was to comprise eight white British and eight Pakistani women who had accessed preconception in primary care, eight of each group who had accessed the service in secondary care and eight of each group who had not accessed PCC and drawn from the primary care setting. Interviews with stakeholders were not conducted because the study closed earlier than originally anticipated.

### Characteristics of the research participants

Demographic variables are referred to in the findings, when relevant. *Table 5* summarises the characteristics of the 12 research participants. Participants were aged between 23 and 39 years. All but four participants described themselves as white, two women described themselves as British Pakistani, one woman described herself as Pakistani and one woman as mixed race. All of the women interviewed were married or in a relationship. The educational level of women varied and most were in employment ( $n = 7$ ); three women described themselves as housewives, one participant was a student and one was unemployed. Only three women had T2DM and the remainder had T1DM. Women had lived with a diagnosis of diabetes mellitus for between 2 and 26 years. Just over half of the women ( $n = 7$ ) were using an insulin pump to help control their diabetes mellitus, one woman was just on insulin injections, another three were on insulin injections and taking metformin hydrochloride, and one woman was taking metformin hydrochloride only. Two of the women were nulliparous, eight of the women were primi- or multiparous and seven women were pregnant at the time of the interview (five of these were parous and two nulliparous). Of the parous or currently pregnant women, six had planned all of their pregnancies, one had not planned her pregnancy and three women had both planned and unplanned pregnancies at different stages of their reproductive life course. Obstetric histories were varied and three of the women had experienced a miscarriage. Of the eight parous women, all had experienced one or more caesarean sections. Five of the women in the study group had not attended PCC but the remainder ( $n = 7$ ) had. When women were asked about their future pregnancy plans, four of the women were not sure about their plans for future pregnancies. Four were decided on having no, or no more, children and four women thought they would want a future pregnancy. Contraceptive use was varied among the research participants in the study. One woman had been sterilised and two women did not use any contraception. Other forms of contraception included the contraceptive pill ( $n = 3$ ), the contraceptive injection ( $n = 1$ ), condoms ( $n = 4$ ) and an intrauterine device (IUD) ( $n = 1$ ). White British women and women with T1DM are over-represented in the study group. Attendance at PCC is also over-represented and, in the general population, approximately one-third of women with pre-existing

TABLE 5 Characteristics of research participants

| Name <sup>a</sup> | Age (years) | Recruited from | Ethnicity | Marital status  | Education level  | Occupation   | Diabetes mellitus type (duration in years) | Pregnancy history                       | Planned pregnancies | Delivery mode             | Future pregnancy plans | Attended PCC | Medication for diabetes mellitus              | Contraception type |
|-------------------|-------------|----------------|-----------|-----------------|------------------|--------------|--|---|---------------------|---------------------------|------------------------|--------------|---|--------------------|
| Aziza             | 34          | SC             | BP        | Married         | GCE A level      | Housewife    | 1 (23)                                     | Four children                           | No, yes, no, yes    | C-s, I, V                 | No                     | Yes          | Insulin pump                                  | Sterilised         |
| Carol             | 39          | SC             | W         | In relationship | PGCE             | Employed     | 1 (26)                                     | Pregnant                                | Yes                 | –                         | Not sure               | Yes          | Insulin injection and metformin hydrochloride | Pill               |
| Lilly             | 35          | SC             | W         | Married         | BTEC and Diploma | Employed     | 1 (24)                                     | One child; pregnant                     | Yes                 | C-s                       | Not sure               | Yes          | Insulin pump                                  | Condoms            |
| Mary              | 26          | SC             | W         | Married         | GCSE and NVQ     | Employed     | 1 (15)                                     | One miscarriage; one child; pregnant    | Yes                 | C-s                       | Not sure               | Yes          | Insulin pump                                  | Pill               |
| Noor              | 35          | PC             | P         | Married         | Degree           | Housewife    | 1 (15)                                     | One miscarriage; one child              | No, yes             | C-s                       | Yes                    | Yes          | Insulin pump                                  | No                 |
| Rani              | 36          | SC             | BP        | Married         | None             | Housewife    | 2 (10)                                     | Six children; one miscarriage; pregnant | Various             | 2 x V<br>2 x C-s<br>2 x I | No                     | No           | Insulin injection and metformin hydrochloride | IUD                |
| Rose              | 25          | SC             | W         | Married         | Masters          | Student      | 1 (6)                                      | Pregnant                                | Yes                 | –                         | Yes                    | No           | Insulin pump                                  | No                 |
| Sasha             | 27          | PC             | W         | In relationship | MBChB            | Employed     | 1 (14)                                     | None                                    | –                   | –                         | Yes                    | No           | Insulin pump                                  | Pill               |
| Sheila            | 23          | SC             | M         | Married         | Apprenticeship   | Employed     | 1 (12)                                     | None                                    | –                   | –                         | Yes                    | Yes          | Insulin injection                             | Condoms            |
| Stephanie         | 29          | SC             | W         | Married         | GCE A level      | Employed     | 2 (4)                                      | One child; pregnant                     | Yes                 | C-s                       | No                     | No           | Metformin hydrochloride                       | Injection          |
| Susie             | 37          | SC             | W         | In relationship | Diploma          | Not employed | 2 (1)                                      | Twins; pregnant                         | No                  | C-s                       | No                     | No           | Insulin injection and metformin hydrochloride | Condoms            |
| Xena              | 38          | SC             | W         | Married         | Degree           | Employed     | 1 (22)                                     | 1 child                                 | Yes                 | C-s                       | Not sure               | Yes          | Insulin pump                                  | Condoms            |

–, participant was nulliparous at the time of interview and so there is no delivery mode to report; A level, Advanced level; BP, British Pakistani; BTEC, Business and Technology Education Council; C-s, caesarean section; GCE, General Certificate of Education; GCSE, General Certificate of Secondary Education; I, induced; M, mixed race; MBChB, Bachelor of Medicine and Bachelor of Surgery; NVQ, National Vocational Qualification; P, Pakistani; PC, primary care; PGCE, Postgraduate Certificate in Education; SC, secondary care; V, vaginal delivery; W, white.

<sup>a</sup> All names are pseudonyms.

diabetes mellitus attend PCC. However, there are more women with T1DM in the study group and such women are more likely than women with T2DM to attend PCC.

## Profiles of the research participants

A profile of each research participant is included below.

### Aziza

Aziza was 34 years old, British Pakistani, married, educated to General Certificate of Education (GCE) Advanced level (A level) standard and described herself as not working and a housewife. She had been diagnosed with T1DM 22 years previously. The interview was conducted in English and Urdu. She had been referred by the hospital diabetic team to PCC. After her fourth child was born, she was started on an insulin pump.

Aziza was multiparous and previously had four pregnancies. Her first child (unplanned) was born by elective caesarean section for pregnancy-induced hypertension at 31 weeks of gestation – a girl who weighed 2 lb at birth who was in a neonatal unit for 3 months. She expressed breast milk for the neonatal unit. Her second child – a boy aged 8 years – was planned and was born at 38 weeks following induction (4 days of labour) and weighed 5.5 lb. She refused a caesarean section. Prenatally, he had a diagnosis of hypoplastic left heart but was fine at birth. The third child, unplanned, was 5 years old at interview and the birth was induced. At birth he weighed 8 lb 14 oz. The fourth pregnancy was planned and the baby was born at 38 weeks by a normal delivery, weighing 8 lb 3 oz. He was 18 months old at the time of interview.

Two of the pregnancies were planned and two were unplanned. After the birth of her fourth child, Aziza was sterilised, after much prevarication.

She expressed concerns about the stigma associated with diabetes mellitus.

### Carol

Carol was 39 years old, white British, single but cohabiting and was studying for a post-graduate degree and was employed. She had been diagnosed with T1DM 27 years previously. She took metformin hydrochloride, insulin aspart (NovaRapid®; Novo Nordisk, Bagsværd, Denmark) and insulin detemir injections (Levermir®; Novo Nordisk). Carol was also taking levothyroxine sodium. She attended PCC for 6 months over 1 year before she conceived. She gave up smoking in the hope of getting pregnant.

She was primiparous and 6 months pregnant at the time of interview. She had been taking the contraceptive pill and stopped for a long time before becoming pregnant.

She found the Diabetes UK website unhelpful.

### Lilly

Lilly was 35 years old, white British, married and educated to higher education level and employed. She had been diagnosed with T1DM 24 years previously and had been on an insulin pump for 12 months. She had been referred to PCC by her diabetic practice nurse.

She was multiparous, with a boy aged 2 years and 2 months who had been born by caesarean section following pre-eclampsia. Lilly was in the third trimester of pregnancy and had chosen an elective caesarean section for the current birth.

She had planned both pregnancies and they used condoms as contraception.

**Mary**

Mary was 26 years old, white British, educated to National Vocational Qualification (NVQ) level and employed. She had been diagnosed with T1DM 15 years previously. She had used an insulin pump for 6–7 years and attended PCC before her first pregnancy when the pump was prescribed.

Mary was multiparous and had been pregnant three times; the first pregnancy ended in a miscarriage and the second resulted in a live infant who was 2 years old at the time of the interview and was delivered by caesarean section for breech presentation. Mary was in the third trimester of pregnancy at interview.

She used the contraceptive pill and had planned all three pregnancies.

**Noor**

Noor was 35 years old, Pakistani (Kashmir), Urdu speaking, born in Pakistan and moved to England after her marriage. She had been educated to postgraduate level but was not employed. She had been diagnosed with T1DM 15 years previously and had suffered side effects, having a kidney removed in Pakistan. She was taking statins and her GP referred her to the hospital diabetic team. She had been on an insulin pump for 3 years and had stopped using it months before the interview because of some localised bleeding from the site and the inconvenience in handling her toddler. Noor had attended PCC.

She was multiparous, with her first pregnancy ending in an early miscarriage at 8 weeks and one living infant aged 1 year who was delivered at 36 weeks' gestation by caesarean section because of fetal distress and early spontaneous rupture of membranes.

In terms of pregnancy planning, she wanted another child. She did not take any contraception.

**Rani**

Rani was 36 years old, British Pakistani, married twice, with two children by her first marriage. She said she had no qualifications and was unemployed. She had been diagnosed with T2DM 10 years previously and was taking insulin injections and metformin hydrochloride tablets. During her third pregnancy she was diagnosed with gestational diabetes mellitus but had a strong family history of diabetes mellitus and had some renal damage. She has hospital contact every 2 weeks. She expressed dissatisfaction with her GP care.

Rani was multiparous, having had seven pregnancies and six live children. Two were delivered by caesarean section and four were normal births. Rani's children's were aged 18, 15, 9, 7, 6 and 3 years. Her third pregnancy ended in miscarriage. Her fourth child weighed 11 lb at birth and was in special care for several weeks. She was about 4 to 5 months pregnant at the time of interview.

Rani claimed to have planned all of her first five pregnancies. She had a coil fitted but this failed twice, resulting in her sixth and seventh pregnancies. She planned to be sterilised after the current pregnancy.

**Rose**

Rose was 25 years old, married, white British and a Doctor of Philosophy student. She had been diagnosed with T1DM 6 years previously and also had an autoimmune liver disease and coeliac disease. She used an insulin pump of Novarapid prescribed by the PCC.

Rose was primiparous and about 11 weeks pregnant.

She had not used any contraception but did not necessarily want to get pregnant.

### Sasha

Sasha was 27 years old, single, white British and employed. She had been diagnosed with T1DM 14 years previously and used an insulin pump delivering a subcutaneous infusion of Novarapid. Her care was managed by her GP with 6-monthly specialist diabetes mellitus hospital check-ups.

In terms of obstetric history, she was nulliparous.

She had no immediate pregnancy plans but would consider children in 3–5 years. She was taking the contraceptive pill.

### Sheila

Sheila was 23 years old, white British and married to an Asian man. She was educated to NVQ level and was employed. She had been diagnosed with T1DM 12 years previously and used Novarapid injections. Her diabetes mellitus was unstable and she had a strong family history of diabetes mellitus. She had been referred to PCC and had anxiety about the risks of diabetes mellitus.

She was nulliparous and not actively planning to get pregnant but her husband was hoping for children.

They used condoms for contraception.

### Stephanie

Stephanie was 29 years old, married, white British, educated to GCE A level standard and employed. She was diagnosed with T2DM and taking metformin hydrochloride tablets. She was diagnosed with gestational diabetes mellitus with her first pregnancy so had been diabetic for over 4 years. She attended both the GP and hospital for diabetes mellitus care. She had no awareness of PCC.

She was multiparous, had one child aged 4 years who was born by caesarean section and admitted to neonatal care for hypoglycaemia at birth. At interview she was 34 weeks pregnant.

She planned her pregnancies and used Depovera as contraception.

### Susie

Susie was 37 years old, white British, educated to diploma level, living with her partner and unemployed. She has had T2DM since being diagnosed with gestational diabetes mellitus with her first pregnancy 17 months previously and had been on metformin hydrochloride tablets, which had just been changed to insulin for the current pregnancy. She was unaware of the risks associated with diabetes mellitus and pregnancy. She did not use PCC.

Susie was multiparous, had twin boys who were born by caesarean section and spent 2 weeks in the neonatal intensive care unit. They were aged 17 months. Susie was 8 weeks pregnant at the time of interview.

Neither pregnancy was planned and they used condoms as contraception.

### Xena

Xena was 38 years old, white British, a graduate and employed. She had been diagnosed with T1DM 22 years previously. Xena attended a thyroid clinic, diabetic clinic and an antenatal clinic. She did not use her GP for any of this care. She was put on an insulin pump 3 years before conception. She had attended PCC.

Xena had a 1-year-old son who was born at 36 weeks' gestation by elective caesarean section. This was a planned pregnancy.

She did not want to get pregnant at the time of interview and she and her partner were using condoms for contraception.



## Thematic analysis of the interviews with women

### *Pregnancy choices and contraception*

#### Planning

Participants shared a range of obstetric histories. Of the 12 women who were interviewed, two were pregnant for the first time, six were pregnant with their second, third, fourth or sixth child, two women were not pregnant (one of whom was hoping to conceive whereas the other had no immediate plans or long-term relationship but wanted children in the future), one woman had one child but did not have immediate plans for more, and one woman had four children and had since been sterilised.

Preconception care might be relevant to all women with pre-existing diabetes mellitus, but not all women planned to get pregnant. The profile of women with diabetes mellitus can be diverse as the above summary highlights and some women disclosed at interview that their pregnancies were planned whereas others said they were not. For women with a history of more than one pregnancy (multiparous), not all of their pregnancies were planned, reflecting the reality that planning is not just about individual behaviour and choice. The same woman/couple might behave differently at different times and the findings show diversity both within the group of participants and at the level of the individual. As discussed in the literature above (see *The complexities of pregnancy planning*), pregnancy planning is complex and diverse and women do not necessarily make choices consistently and according to one rational plan. Therefore, in terms of planning services and support it is unhelpful to assume that they do. For example, illustrations from the data show that Rani, a British Pakistani woman with six children, had T2DM, had suffered a miscarriage, was pregnant at the time of interview and had planned five of her seven pregnancies. The two unplanned pregnancies were a result of failed contraception, as discussed below. When asked specifically about pregnancy planning she said 'Hmmm this one and the last one wasn't but the rest was'.

Susie, with T2DM, had twins and was 8 weeks pregnant at the time of interview. Neither pregnancy was planned as she disclosed:

*Interviewer: Erm, with your pregnancies, erm, were they planned?*

*Susie: No [. . .] [D]efinitely not!*

*Interviewer: Both of them weren't planned?*

*Susie: Yeah, definitely not!*

Aziza was a Pakistani woman who had T1DM and had four children, two of whom were planned and two who were not, as she explained:

*Interviewer: OK and were they all planned pregnancies?*

*Aziza: Two were, two weren't [. . .] eldest wasn't planned [. . .] yeah and she was born at 31 weeks – pre-eclampsia. [. . .] The second one was planned. He was born at 38 weeks err – he weighed about 5 and a half pounds. [. . .] Third one wasn't planned. I've got two it's enough you know [. . .] third one was born 37, 38 weeks. She weighed a whopping 8, 14 [. . .] and the youngest one was planned and he weighed erm 8, 3.*

#### Contraception

When participants were asked about their contraceptive choices, their answers varied. For example, the most common form of contraception was condoms, which were used by four participants, and the next most common was the contraceptive pill, used by three women. Surgical sterilisation was the choice of two women, one of whom was pregnant, whereas another had been sterilised following her fourth

pregnancy. Two participants did not take any contraceptive precautions. Significantly, some of the participants who did not take precautions did not necessarily want to get pregnant.

For example, Noor was a Pakistani woman with T1DM who had a history of miscarriage and kidney disease. She claimed to have planned her pregnancies but at interview disclosed that she and her (Pakistani British) husband did not use contraception and talked vaguely about how her husband ‘(l)s against this thing’ and also that she was scared of taking any more medication: ‘I only have one kidney now, so for this reason I am scared and don’t want to take any extra medication’.

Susie, who was a white British woman, had T1DM and was 6 months pregnant. She had been advised that she could not conceive, as she explained:

*Susie: Yeah, because I got told I had, before I got pregnant with my twins, I had a large fibroid which I’d been carrying for at least 5 years but nothing was done about it until obviously the year before I was in that much severe pain [. . .] that erm, something had to be done, then in the March I went to have a test with gynaecologists, and they says there was 97% chance of me not ever having any children.*

*Interviewer: 97%?*

*Susie: Yeah. So then . . . but in the June, that’s why it was such a shock because in the June I fell pregnant . . .*

Rose, who was white British, had T1DM and also had an immune liver disease, expressed uncertainty about her ability to conceive, as she explained:

*So we didn’t know how that was going to affect like I could get pregnant, being on . . . I’m on high doses of steroids and immune suppressants and they can obviously affect your fertility and things . . . we were trying not to get our hopes up too much . . . we were very happy when we found out . . .*

Rani, with T2DM, talked about how the coil had ‘failed’:

*Rani: Yeah, after the younger one, 3 years now and it was 3 years – 2, 3 years when I had it . . . when I got pregnant with her.*

*Interviewer: Oh so you had had the coil for 2, 3 years and then you had got pregnant?*

*Rani: Yeah*

*Interviewer: OK, erm did they take it out for your birth . . . for the birth?*

*Rani: [T]hey couldn’t find it [. . .] they didn’t find it and err same for this one, I went for a scan they said they sort of think it’s gone a bit down [. . .] but then I went for another check-up and they can’t find it.*

These quotations illustrate some of the complexity and diversity involved in making contraceptive choices alongside managing a long-term condition. Although these choices are not confined to people with diabetes mellitus, some of the women appeared to be confused about their fertility status, which suggests the need for a more nuanced approach to preconceptual care that acknowledges the need for clear guidance on women’s fertility status. The women interviewed did not appear to make a link between the need to prevent pregnancy and the use of a reliable contraception.

## Enablers to preconceptual care

### Referral

Participants talked about their awareness of preconceptual care – and mostly awareness seemed to be raised during hospital diabetic care. Indeed, the data show that being referred to PCC was the most common reason for women's attendance. Although it seems to be self-evident that women who were referred to PCC and were recruited to this study through secondary care were in the majority, that is 10 out of 12, not all of these women were at the preconception stage. Some had been referred during their pregnancy and others between pregnancies. In the case of the two women with no previous obstetric history, one (a medical practitioner) told us she would attend PCC if and when she planned to get pregnant and the other was attending PCC at the time of interview. If recruitment had continued, data on this would have revealed more information on the lack of uptake as more women in that target group would have been interviewed. However, it is clearly a mistake to assume that women who attend PCC clinics do so from awareness of the existence and usefulness of such clinics, or at the preconception stage, which raises the question of how to get the timing right and who is responsible for any referral.

For some participants, the distinction between PCC and what was diabetic antenatal care was not always clear, as Xena, with T1DM, and who had one child explained:

*[E]rr it all kinda blurred into one really, because, because Dr Ahmed is my pump consultant and my preconception consultant, often I've found it difficult to pick apart which appointment was for which really, erm, because I was always having blood tests for one or the other, but because he oversaw both actually that didn't matter, so and the care was, the care was really good and the nurses were fantastic as well so I didn't have any problems. I knew where I could go to if I needed to.*

Xena

Lilly, who had been diagnosed with T1DM 24 years previously, had been referred by the diabetes mellitus nurse at her GP practice 2 years before her first child was born and was in the third trimester of her second pregnancy at the time of interview. Lilly was very pleased with the way the service addressed all of her needs, as she explained:

*Lilly: [laughs] if I needed a dietician, I've had a dietician, if I needed my eyes done, I've had my eyes done, erm anyone I've ever needed to speak to, or bloods done, or anything like that, they've just always been there or I have been referred and helped as soon as they could yeah.*

*Interviewer: Erm what do you think helps facilitate the care?*

*Lilly: The staff, the people, they are just lovely. Nothing is too much trouble.*

Although the data show mixed views about the experience of PCC, and some confusion about its distinctiveness, it was clearly highly appreciated by some women. However, worthy of note is that there did not appear to be a direct correlation between the length of time women had managed their diabetes mellitus and the way in which they valued PCC. Women with lots of experience in managing diabetes mellitus still valued attending PCC, although, the same could be said for specialist diabetes mellitus care. However, those who valued their care did not always specifically highlight how it prepared them for pregnancy. It is reasonable to assume that women who regularly attended the hospital diabetic clinic would be referred to PCC, but sometimes this appeared to comprise the same team. Indeed, there was an obvious overlap between the role of practitioners in diabetic care and preconceptual care as well as that of antenatal care when women had been referred 'late'.

## Blood glucose control

Blood glucose levels seemed to dominate the discussion on preparing for and managing pregnancy. Seven out of the 12 women interviewed were using an insulin pump and valued the improved blood glucose control they gained from continuous insulin administration. Four women used insulin injections whereas one took oral medication in the form of metformin hydrochloride.

The first quotation from Carol, who had been diagnosed with T1DM 26 years previously (for which she administered subcutaneous insulin injections and took metformin hydrochloride tablets), was at the end of the second trimester of her first pregnancy, reflects an improvement in her blood glucose control that she attributed to regular monitoring:

*Carol: Loads better yeah it's a good, eh, it's a good kick in the right area [laughs] [. . .] to err to help sort of make it go in the right direction. But my control is the best it's ever been . . . so it's been a really good thing actually. I'm quite healthy anyway but I'm healthier now than I've even been.*

*Interviewer: Yeah, are you going to try maintain this as well?*

*Carol: Yeah, hopefully yeah, I mean I don't, I haven't made major changes so but my HbA<sub>1c</sub> is down to 6.9, which is a lot lower so yeah hopefully carry on with it and not having as many hypo's and stuff like that so [. . .] I'm hoping to continue with it . . .*

Rose, who was in the first trimester of her first pregnancy, had been diagnosed with T1DM 6 years previously, used an insulin pump and attended PCC from the time of getting married. She explained how the pump helped her:

*Rose: Yeah so – when I, when I got married because we were Catholic we knew we wouldn't be using contraception, I joined the preconception clinic. Erm – so I think I had my first meeting with them a week after I was married or something, so I've been seeing them periodically in the run-up you know and err – I got switched over from injections to a pump [. . .] and that massively improved my control and that's it beeping now, sorry [laughs].*

*Interviewer: [laughs] Erm right . . . so what was your diabetes care like before your pregnancy?*

*Rose: So I was on . . . I was on . . . except for the year before I have been on injections, I have been on Lantis and Novarapid . . . erm I had periods when it wasn't so good you know, you get a bit bored of doing it all and especially when I was younger and err . . . but generally it was it was quite good and I was happy . . . just sort of got on with it . . . and then, like I say, July last year I moved over to a pump and my control got a lot better, so a lot more . . .*

*Interviewer: Yeah so why didn't you use the pump earlier?*

*Rose: Erm just 'cos no-one had really suggested it . . . I mean they obviously take a lot of funding and it's a lot of work to get, you have to go on courses and it's a lot more, more intensive you know you can't, with the injections you can be a bit more like freely and easy like if you're having a bad day and you don't manage it that well it's not that big a problem, but with the pump you have to pretty much be on it all the time and you know, you, you can't just fudge it, you know you have to keep testing your blood, keep making the adjustments, erm so it was really when, when we're looking at the idea of getting pregnant that, erm, Dr Ahmed really started pushing for a pump.*

Although several participants reported that using an insulin pump to deliver continuous subcutaneous insulin helped with their blood glucose control, there seemed to be different levels of ease of access to pumps.

Many participants were experts in their condition, having lived with diabetes mellitus and managed it clinically in terms of blood glucose measurements and adjustments to insulin rates alongside diet for many years. Among the nine women in the study with pre-existing T1DM, disease duration ranged from 2 to 27 years. Nine women had been diabetic for over 10 years, of whom four women had had diabetes mellitus for over 20 years and all were under the care of specialists in diabetic care. Despite their level of knowledge, some women clearly found attendance at PCC helpful in terms of the impact on blood glucose control and having folic acid prescribed to prevent neural tube defects. Less obvious, as discussed in the section below, is the impact on 'lifestyle' changes even though most women were aware of the need to make changes. For those with T1DM, these changes were part of their understanding but they were made more aware of their significance on pregnancy outcomes from discussion with specialist carers.

The data showed that being experienced in the management of diabetes mellitus over many years and understanding how it affected them as individuals, did not always translate into easy control of blood glucose levels. Furthermore, the data showed a range of experiences and levels of expertise in diabetes mellitus and how it affected each individual, and the participants with T1DM since childhood who were familiar with its management still described themselves as unstable insofar as their blood glucose levels fluctuated greatly, whereas others seemed to have better control by such things as the use of a syringe pump.

The following quotation from Sheila is a good illustration: 'Yeah, my blood glucose levels. I think it's getting them under control so it's probably about time to do it now . . .'.

### Living with diabetes mellitus

When asked about their lifestyle, participants translated this into a focus on diet and exercise. As with blood glucose control, diet, weight control and exercise would have been something with which all people with T1DM were aware. However, in the context of pregnancy, despite their focus in answering the question, it seemed that not all participants considered themselves able to control the outcome by adapting their diet and exercising more. Rani had six children but seemed unable to exercise:

*Well I can't do much of exercise . . . I mean I have got a back problem as well like slipped disc and err exercise, I used to go to the gym and I used to go swimming as well but eh to be honest I don't do anything now I just . . . too lazy [. . .] I feel weak in myself I just – even now my daughter has gone for a walk and she was telling me to come and I said no I can't go – I just try to walk to the kitchen and living room.*

Rani

She went on to explain:

*[Be]cause of my health I sometimes feel dizzy at times, I just feel weak in myself [. . .] so I don't go out much.*

Rani

Lilly, with T1DM, talked about the influence of a dietitian she saw at the hospital when she became pregnant:

*Erm . . . she got me thinking about changing from white breads to whole grains and things like that. I used to be a gym bunny erm and then when I changed my job, I broke my arm really badly and changed my job at the same time so I kind of lost track of all that a little bit erm . . . and then . . . I think I started walking, more actively walking and doing . . . just incorporating exercise in my everyday life. Walking to work rather than driving to work and things like that and that was just from encouragement from the hospital . . .*

Lilly

Carol, also with T1DM, described the changes she had made:

*Erm I gave up smoking about 6 months before I became pregnant, but I've been a smoker kind of on and off throughout. Quite a long time. Erm I haven't drunk at all since I have become pregnant not like not a drop – so no alcohol which is great, erm no caffeine. So yeah, decaff. Everything [. . .] diet not massive 'cos I do fairly healthy diet anyway. Swimming I've always done so I'm carrying on with that. Err I used to cycle but now I don't cycle 'cos I'm pregnant. 'Cos it's a bit, a bit unsafe.*

Carol

Susie, a woman with T2DM who had twins and was 2 months pregnant at the time of interview, disclosed the advice from her midwife to lose weight:

*I'm trying to erm lose weight. My midwife told me that I can go to Slimming World, but which I need to speak to her about. [. . .] But I'm also going to do some exercise, and that because I have got lazy, so you know that. My err diet has changed as well. I'm trying not to eat so much fatty food.*

Susie

### Awareness of the risks associated with pre-existing diabetes mellitus

Being aware of the risks associated with pregnancy for women with diabetes mellitus could be an incentive to attend preconceptual care and to follow the advice received. However, for those who were not aware of the existence of PCC ( $n = 4$ ), this does not apply. At interview, and to varying degrees, women seemed to be conversant with and cited the risks associated with pregnancy. Shelia was white British and married to an Asian man. She had had T1DM for 12 years and was attending PCC because she was referred by her GP and wanted to get her blood glucose under control before conceiving, as she claimed that she had never had it under control and did not want her baby to 'get complications'. For her this control was essential as she said 'Hmm. I don't know it's just crucial that you've got your sugars under control . . .'.

Lilly, who had T1DM, had one child and was 7.5 months pregnant. She had learned about the risks through preconceptual care:

*I didn't know before preconception. Oh, I had an abundance of leaflets to look at. [. . .] You know these little lives could be deformed just 'cos you can't be bothered to look after yourself and you could have done things wrong, couldn't you? Just 'cos mummies can't be bothered [. . .] yeah, and think it's not going to happen to me. 'Cos it can and it does otherwise the research would be out there, would it?*

Lilly

Although clearly dissatisfied with her experience of PCC as discussed later, Carol, who was 6 months pregnant with her first child, had been diagnosed with T1DM 26 years previously and seemed to be better informed about the potential risks:

*Erm, I think I've got a higher risk of higher weight birth child due to sugars being higher, erm, possibly a higher stillbirth rate, especially with my age as well, nearly 40. Erm, apart from that, I'm not really sure. Apart from the fact they might push me to have a caesarean [. . .] which I don't want. [. . .] I know about obviously early formation of the baby and the structure and stuff. And, erm the lower the sugars the better the chance of nothing going wrong there with erm, the heart and stuff like that.*

Carol



Sasha, a trained doctor with a 14-year history of T1DM, at the time of interview was not planning to get pregnant but was quite well informed and talked about the risks for pregnancy from T1DM:

*Oh risks, so congenital birth defects, things like spinal neural tube defects, erm having heavy [. . .] erm . . . I think that was the main thing that I was worried about, because I have been joking with my friends that I will be having a C-section [caesarean section] for my big baby and then when the baby is born will give me hypoglycaemia, erm and also about increased risk of miscarriage and stillbirth.*

Sasha

Stephanie, who had T2DM, stated that her first baby had already experienced complications from diabetes mellitus and was born with hypoglycaemia and had to spend 1 week in the neonatal unit, as she explained:

*So, obviously that's a risk factor and then you've also got the risk factor of if the diabetes is not properly controlled during pregnancy then the baby can come out with diabetes themselves . . .*

Stephanie

However, despite their awareness of diabetes mellitus and its impact on health and well-being, not all participants were fully aware of the risks associated with diabetes mellitus and pregnancy. Susie, who had T2DM, had limited awareness as this quotation illustrates:

*I know the baby will be big. [. . .] [Laughs] It will be a big baby – obviously because the placenta, the . . . Oh, what's it called, something is not working properly. I don't know. My mind's gone blank.*

Susie

Despite having expertise in diabetes mellitus and the associated risks at the time of pregnancy and birth, for some women there was a tension between seeing themselves as able to make a difference to outcomes through their actions and being in the hands of a higher power. This might relate to their belief system, and/or fate, which also could be a dominant force in deciding outcomes. In this way, biologically determined medical discourses might conflict with cultural and religious ones. However, this does not necessarily mean that they were mutually exclusive and the domination of such influences could fluctuate.

Aziza was a British Pakistani woman with four children who had been diagnosed with T1DM 23 years previously. She talked about how her second child was expected to be disabled and described what happened:

*Aziza: [E]rm the second, baby number two, my son, with him at his 36 weeks, was he 38 weeks? At his 36 or 38 week scan, before that everything was fine, they said he's got something called hypoplastic left heart syndrome, that's when the left side of the heart is unformed [. . .] so er then they sent me to, two people at hospital did the scan said the same thing. As far as he was inside me he was fine, but once he was born he would find it difficult to for – his heart to beat and he would have erm open heart surgery, sent me to another hospital, the specialist they did the scans, same thing. I said I've got 2 weeks what are the chances that his heart would form? 'Cos one side was unformed – they said it's too late now, if they would have picked it up earlier, terminated the pregnancy.*

Interviewer: Really?

*Aziza: Yeah, 'cos the eldest child who has survived is about 6 years old. They don't make it past that [. . .] anyway I said no I don't wanna know anything. Those were the 2 difficult weeks of my life. I said no, if there's a God up there, nothing is going to happen to my baby. Otherwise I'm gonna go away from faith.*

After several failed inductions, Aziza's baby was delivered by caesarean section and, as she explained, there was:

*Nothing wrong with him whatsoever! That really did scare me in thinking if they had found out earlier they would have got rid of my baby when there was nothing wrong with him.*

Aziza

Although awareness of risks might serve as an incentive to attending PCC for some participants, this was where they first learned about the detail of those risks. The interviews did not reveal a comprehensive understanding of the risks; at least, when asked, most women did not articulate the risks in any detail. The dominant message they seemed to have taken on board was that high blood glucose levels in women with diabetes mellitus can cause complications in pregnancy. Most women who are pregnant and those who attend PCC before pregnancy are prescribed folic acid. The women interviewed did not offer explanations for taking folic acid when asked about risks but there seemed to be recognition of the need to take it. For some there was confusion about how long they should take folic acid before becoming pregnant and some women started taking it only when they knew that they were pregnant. It seemed to be the case that women who received preconceptual advice were prescribed a higher dose of folic acid before becoming pregnant – but this was not possible for women who had not planned to get pregnant and so were referred later and, consequently, started taking folic acid later. The interview data do not support an overt awareness of the increased risk of neural tube defects (or other teratogenic effects) for women with diabetes mellitus in pregnancy. This does not necessarily translate into a lack of understanding on their part, but when invited to talk about risks, this was mentioned by only two participants (both with T1DM): Sasha and Carol.

As stated, the focus of concern for women who attended PCC was on blood glucose control and this is something that will have been part of living with diabetes mellitus for women who had diabetes mellitus, many of whom seemed to struggle with good control and sought extra help and support when they were hoping to get pregnant or in the early stages of pregnancy and recognised the risks associated with high blood glucose.

### Barriers to preconception care

#### Lack of awareness

The data showed that the main reason women might not attend PCC was because of a lack of awareness. As illustrated in the section above, the responses from those who attended PCC suggest that discussions with professionals about pregnancy resulted in them being made aware of the necessity of the service. Clearly, the three participants with gestational diabetes mellitus, who were recruited as women with T2DM, were aware of the need to control their diabetes mellitus for subsequent pregnancies.

It is worth noting that for Rani, a British Pakistani woman with T2DM who was 4 months pregnant with her seventh child, there was confusion about her diabetic status, as she reported:

*[S]o if you have got diabetes you should go on regular check-ups, it's been a year or so they've took me off the list for diabetes, I've . . . and nobody has been calling me in [. . .] and I didn't know, no blood tests nothing for about a year and a half, then I went back to my GP, and I says I need to be referred, either you guys check me or send me back to the diabetic clinic because I didn't know what's going on and I'm always sleeping like all the time [. . .] I don't know what's going on like, whether my sugar's high, low or what and, eh, then they referred me back last year I think, last year . . . last year, I think, I went to my GP and they referred me back to the diabetic clinic and then every 3 months I was going there.*

Rani

Rani had been diagnosed with gestational diabetes mellitus during her third pregnancy, which resulted in a miscarriage.



### Logistics of attendance

Some women talked about the practical issues associated with being able to attend clinics on a regular basis. Clearly, for those in paid work this raised an issue of the need for their employers to be flexible and allow them to attend, but the participants who talked about this told us they adjusted their working hours to suit attendance. In terms of occupational status, seven of the women interviewed were in paid employment. Three described themselves as housewives, one as unemployed and one was a student. Most women mentioned the need to attend fortnightly during pregnancy. (For women with T1DM, when not pregnant, attendance seemed to be 6-monthly.) Lilly, who had T1DM, was pregnant with her second child and worked part-time but found her managers very accommodating – as she told us:

*Work's brilliant, they are really good. They erm, they'd never complain – as long as I provide letter, that that's where I'm going, they've never complained. They've never said 'no', even with me going every 2 weeks now to the hospital there's never been any issues. But then maybe it's because I'm never off sick, my attendance is good and if I can help outside of my normal working hours, I will. And sometimes without being paid. Like I do summer schools as well [. . .] so it swings things in roundabouts there.*

Lilly

Some women talked about the different clinics they attended, such as antenatal care and diabetes mellitus care, and having to attend up to three clinics if they had other specialist service requirements. Xena, who had T1DM, one child and was in paid employment, had overcome this by being able to combine visits. As she explained:

*I have always made an effort to go to all my diabetes appointments, erm . . . when I was pregnant the . . . there was issues because of the frequency of appointments and also by the end of my pregnancy I was under three different clinic as well. Erm but as soon as I sort of mentioned that I was having issues, people helped me sort of streamline all of the appointments.*

Xena

However, she still had to manage different attendances on different days which created problems with managing her job:

*So I had to juggle three clinics, was there another one? I can't remember now. I felt like we should just pitch a tent in the car park and live there really.*

Xena

It was also the case that being unable to park or the cost of parking combined with the unpredictably long waits made attendance difficult and sometimes expensive. This was something that several participants mentioned. Hospital parking is not an issue of concern that is confined to women with diabetes mellitus. It affects everyone who has to attend hospital: inpatients, outpatients, visitors and staff. (This is an issue that the NHS has been trying to address for some time.) To overcome this, some women arranged for a lift to the hospital. Their ability to get a lift depended on their social support structure and whether or not they had someone with a car who was able to take them. It can be easy to underestimate the extent to which relatively small practical barriers can impact on attendance.

The two main barriers, 'lack of awareness' and 'practical issues around attending', were cited as the key reasons for not attending PCC. This is predisposed on PCC comprising visiting a specialist clinic or at least taking some form of action to prepare for pregnancy that reduces the risks associated with diabetes mellitus and pregnancy. The interview data did not reveal the extent to which women took action based on other forms of advice and guidance through such things as websites and social networks. Although the data revealed enablers and constraints, they were difficult to distinguish insofar as there was confusion about the meaning of PCC, where and by whom such care and advice was provided and the point at which it was or was not accessed.

In the next section, the focus is on communication which straddles several dimensions of care but which also offers a perspective that deserves separate treatment.

### *Communication with professional carers: patients or partners*

#### **Communication as care**

The theme of communication that emerged from the analysis straddled many aspects of preconceptual care for women with diabetes mellitus. As already stated, most of the participants had been managing their diabetes mellitus for many years and had varying levels of knowledge and experience. Not all of them had been stable in terms of blood glucose control but they did not necessarily see themselves as lacking expertise. In the previous sections in this report on the quality of the relationship between professionals and women with diabetes mellitus, it is clear that the way in which communication was handled was a key factor in the way women valued the relationship of preconceptual care. Here, the examples that follow highlight how not recognising patients as experts in their own condition can serve as a constraint in accessing PCC. Indeed, for some, this resulted in them not using the service.

At the time of interview, Carol was using insulin injections and metformin hydrochloride tablets to control her diabetes mellitus. She had been diagnosed with T1DM 26 years previously, had been attending PCC when planning to get pregnant but did not really value the experience, as she explained:

*[I]t was things I already knew, but then that's just me being sort of arrogant I suppose, they tried to retrain me with carbohydrate counting and stuff which was helpful erm and I needed to do but erm the HbA<sub>1c</sub> was too high and they just kept telling me that it was too high and I was like well, I already know it's too high [laughs] that isn't particularly helpful [. . .] erm so I didn't feel that supported, it wasn't it was, it wasn't a nurturing thing it was more kind of, I'm not, they weren't being horrible or anything or negative [. . .] but they were just, it wasn't that encouraging, I didn't find so, so I stopped going.*

Carol

Carol's quotation also illustrates the medical focus on blood glucose levels for women wanting to become pregnant. Stephanie had one child and was nearing the end of her pregnancy. She had been diagnosed with T2DM 4 years previously but still experienced frustration and questioned the value of specialist care:

*[R]eally frustrating [laughs] 'cos your sitting there for an hour and a half to 2 hours waiting to be seen by the by the doctors, you eventually get called in, they look at your notes, which has been in my experience, they looked at my notes, the obstetrician said, 'How are you feeling?' and I'm like 'I'm OK.' 'How's baby? Is she moving?' I'm like, 'She's moving, she's fine.' 'OK great!' So going back to the diabetic doctors, 'bloods are fine, no problem at all, see you in 2 weeks!' I'm like I've just sat here for 2 hours [. . .] I could have told you that! [laughs].*

Stephanie

However, for some women, their expertise was respected. Xena, who had been diagnosed with T1DM 22 years previously, explained:

*Yeah, yeah so it's a shared, I've always felt, feel like it's a shared appointment erm, so I can come to them and say this isn't happening or that isn't happening and they can give me some advice and I go oh yeah I should try that, but then I'm, I can be in e-mail contact with them so I have e-mailed the nurses so that I can say this isn't happening or that is not happening so it's much more of a two-way process. Whereas I think if you're a passive patient and you just go because oh no I've got to go, you're not going to get anything out of that kind of appointment.*

Xena

For Xena, being an active participant was important and she attributed part of the notion of shared care to being an active partner and not passive. She went on to say:

*[. . .] [M]y care felt much more like a conversation, it felt more collaborative. I didn't go in and was told I should do this, it felt much more like what's your view, what are you doing, shall we try this? What do you think on it? That kind of conversation.*

Xena

However, Xena had a bad experience with the delivery of her first baby when she went to a different hospital for the elective caesarean section. She explained:

*Xena: So I was in recovery from the minute he was born to about 6 or 7 o'clock in the evening when they moved me onto the ward and then I had some issues with the ward staff as well, so . . . and I don't really remember much of the Wednesday. I remember a team coming over and saying that they are a diabetes team equivalent, but nobody asked me about my diabetes . . . Erm [. . .] but they had never come across anyone with a pump either.*

*Interviewer: Really?*

*Xena: No, so so I've . . . it was really difficult because at H, all the information had gone to H and they, you know there was an expectation about this lady on a pump but at G they didn't really know what to do with me and at the end they left me to it, because the control was fine [. . .] and I knew what I was doing 'cos otherwise they would have put me on a sliding scale and I refused that, I didn't want that, I wanted to be in control of what was going on and my husband knows how to use the pump . . .*

Although Xena was very clear that she wanted to have control over the situation, the quality of her care in labour, according to her, was compromised by the lack of expertise on behalf of the staff at a different hospital.

As with many forms of health and social care, communication is not just about information sharing, but it also forms part of the care. The quality of communication with care givers was a key aspect of the extent to which participants valued the experience of PCC. This quotation from Carol sums up the way in which communication is care:

*[. . .] Erm being able to offer flexible times when people can go is very useful especially when you've got a full-time job erm not having to miss work to go to stuff, so like later appointments or early morning appointments, that kind of thing helps. Practicalities erm . . . and also the kind of manner of the person that's dealing with you em so obviously everybody is nice but some people have got more kind of subtle [laughs] approach and it tends to have better effects I think erm so like people that haven't got diabetes, obviously they know about it but there's a certain understanding that you probably can't quite relate to if you haven't got it. So telling somebody a certain thing is a lot easier than that person actually doing it, so just the way the advice is given and . . . yeah it not being condescending it just being more positive.*

Carol

Participants who had developed a strong relationship with their professional carers and had expertise in their diabetes mellitus talked about care as a partnership, as in the illustrative quotations from Xena above. Others expressed mixed views about its value. For some women, the experience was negative and in the following quotation Rani talked about a different type of relationship, in which she was not an equal partner in her care.

When asked about her GP, Rani told us:

*... well ... I'm not really happy ... I just ... I mean from all the doctors I just like the one lady doctor who really does take care and looks into things ... but there are ... one or two doctors that you know if there's more than one problem you've got they don't ... they don't even let you speak, they just tell you to shut it there that's it ...*

Rani

## Continuity of care

The value of PCC was partly interpreted through the relationship with professional carers. However, another aspect of the quality of the relationship was continuity of care. Carol talked about the value of seeing the same doctor, but there was not the same continuity of antenatal care with midwives, as she explained:

*Erm midwives, I haven't really seen any midwives through the hospital and I have not seen the same midwife. I've seen a different midwife every time. There are specialist diabetic midwives who I met when I first became pregnant and then I haven't seen either of them since, which I thought was a bit strange.*

Carol

Susie, who had twins and was early in the first trimester of her second pregnancy, claimed that she rarely saw the same person twice:

*You know that you don't see the same people all the time, so you know you do see some of the same faces but you never really see the same person.*

Susie

Continuity of care was not just about establishing and maintaining a relationship. Carol saw different practitioners who gave different types of advice:

*Carol: But yeah seeing the same person definitely helps. I did see one other person on my first appointment who told me different stuff to what the current consultant told, tells me ...*

*Interviewer: Hmmm how different?*

*Carol: Erm it was stuff to do with taking tablets, 'cos sometimes I was taking like ... six or seven tablets in the morning [...] and one of the consultants told me that I should take them at separate times periods and like stall it if you like, so not take them all together in one go and then I told that to the present person that I'm seeing and he said, 'Oh don't worry about it, it won't make much difference' [laughs]. [...] So you know two different sort of ideas but erm ... yeah.*

There are several aspects to recognising that communication is part of care. First, it is important for people with long-term conditions to manage their own care most of the time, and building trust is an important part of enabling them to cope at key and dynamic stages in their life. Second, women are more likely to want to attend clinics when they feel they are treated with respect and dignity. Third, alongside choice and control, continuity of care is a major issue in the evaluation of the effectiveness of prenatal, intrapartum and postnatal care and particularly significant with women with diabetes mellitus. Seeing diabetes mellitus as a complication of pregnancy means that women's choice and control might be compromised in the interest of reducing risk, leaving continuity of care as the single most important aspect.

## Summary

The thematic analysis of the qualitative data derived from interviews with 12 women reveals four significant themes. First, the complexity of pregnancy planning is highlighted, demonstrating that pregnancy planning is neither rational nor linear and can vary throughout a woman's life course. Managing contraception in the context of living with a long-term condition is also complex. Second, the data analysis identifies several factors that enable uptake of PCC, which includes awareness of the risks of diabetes mellitus in pregnancy, knowledge about lifestyle and the management of blood glucose levels prior to getting pregnant. Third, a number of barriers to uptake of PCC have also been identified including a lack of awareness of the issues identified above and concerns about the logistical practicalities of getting to and from clinic. Finally, the quality of care provided to women with pre-existing diabetes mellitus has also emerged as a significant theme. Of particular importance here is the quality of the relationship between the woman and her carers and the importance of continuity of care.

## Chapter 6 Discussion, conclusions and implications

In this chapter we identify key issues that derive from the interview data and the systematic review of the qualitative literature and make recommendations for practice and further research. The strengths and limitations of the project are also discussed.

### Discussion

#### *Reconceptualising preconception care*

It is clear that although the following definition referred to in *Chapter 1* of this report highlighted that PCC for women with diabetes mellitus is wide-ranging, there is general agreement that in practical terms, its central tenets typically include genetic and family history risk assessment, immunisation, vitamin supplementation (especially folic acid), smoking cessation advice, and advice on alcohol intake, weight management, diet and exercise.<sup>14</sup> Both the wider definition and guidance agree insofar as the focus is on the actions that are needed for women with diabetes mellitus to reduce risks associated with pregnancy.

What has emerged from the interview data and the systematic review relates to the first point of the NICE guidelines that recommends empowering women by providing information about risk reduction.<sup>14</sup> To be able to make choices that mitigate risks, women need to be aware of many factors about their diabetes mellitus as well as their fertility status and choices – even assuming that they want to and are able to take advantage of them. The findings suggest that the wide-ranging arbitrary way in which women access PCC highlights how the current offering and responsibilities are not meeting the needs of the majority of women with diabetes mellitus. A wider issue is that a coherent and co-ordinated approach is lacking.

Preconception care is not solely located in the preconception clinic, wherever that is based, be it in primary or secondary care. Information on PCC is widely available to women through formal and informal networks. The detail of preconception advice is both complex and open to interpretation, meaning that information is not necessarily consistent, up to date or accurate.

The reconceptualisation of PCC raises the question of who is responsible, and who should be responsible, for this care. It is clear from these report findings that the point at which women with diabetes mellitus access information on risk reduction prior to pregnancy is crucial (i.e. it is vital that information is accessed prior to conception and, ideally, prior to discontinuing contraception). Making the assumption that women with or without their partners follow a linear, rational, decision-making process in terms of when to plan any pregnancies is false. It might be the case for some women at certain points in their reproductive life, but it is not the case for many.

The professional responsibility for reducing risks in any pregnancy has historically belonged to midwives, GPs and obstetricians working together with women. Over time, the shift in emphasis has moved from antenatal to PCC. However, apart from general public health concerns, such as the preventable risks associated with smoking and pregnancy and taking folic acid to reduce neural tube defects, there has been limited success in the PCC service.<sup>49</sup> Women with diabetes mellitus would appear to be more easily identified, at greater risks of complications and, therefore, theoretically at least, more easily targeted.

In summary, implications for practice include:

- Given the different ways that women access information combined with the challenges of providing the right information in a timely way, more consideration should be given to alternative means of providing PCC other than through face-to-face consultation.
- Women with pre-existing diabetes mellitus receive care in both primary and secondary care settings and so to avoid gaps in provision, clear referral pathways for PCC for women with pre-existing diabetes mellitus of childbearing age should exist ensuring that there is clear leadership, responsibility and audit of outcomes.

### ***Pregnancy planning and contraception***

In order for women to be able to make decisions about planning pregnancies, they need to be aware of what risks might be preventable and how. Planning pregnancy is a fundamental first step in preventing or reducing some of these risks.

Both the literature and the interview data highlighted several layers of diversity in the ways in which women plan pregnancies. First, for some women there appeared to be a lack of clarity about their fertility status. Second, some were not necessarily clear about effective methods of contraception for women with diabetes mellitus. Third, personal taste and preference affected choices which meant that contraception sometimes failed either because it was not used or because it was ineffective. Finally, some women who did not want to get pregnant did not take any precautions. As previously stated, what is clear is that they do not necessarily follow a linear and/or rational decision-making process.

Pregnancy planning and contraception are significant in relation to PCC because of the factors listed in the NICE guidelines.<sup>14</sup> Therefore, although it might remain relevant during pregnancy to optimise blood glucose control, take a higher dose of 5 mg of folic acid, change teratogenic drugs to safer alternatives for use during pregnancy, optimise complications and coexisting medical problems, lose weight and stop smoking, the most significant time to do so is prior to pregnancy. This is because teratogenic changes take place in the early weeks of pregnancy when organogenesis occurs. Given that all women with diabetes mellitus who are able to conceive are at the preconception stage, it follows that they need to be aware of pregnancy planning as a fundamental part of PCC.

Furthermore, PCC specialists do not necessarily hold the expertise about pregnancy planning, fertility and contraception that is needed to help women with diabetes mellitus to make sound choices. Diabetes mellitus, pregnancy, fertility and pregnancy planning advice and contraception are specialties in their own right. As with all specialisms, they are also areas in which rapid change might take place and keeping up-to-date is part of professional competence. The person best placed to communicate risks to pregnant women is someone with expertise in pregnancy, diabetes mellitus and contraception.

### ***Responsibility for preconception care***

Recognising that a key part of PCC for women planning for pregnancy is information and guidance on the risks to them and their infant, such information and guidance needs to be available for a significant period before pregnancy. The interview data and systematic review showed a lack of clarity about where women could go for what help and advice. Although that expertise might reside in single professionals, it is more likely to exist within a multidisciplinary team.

As argued above, one difficulty with the shift of focus from antenatal care to PCC for all women wanting to get pregnant is how to target them effectively. Women with diabetes mellitus, as one population group at risk of pregnancy complications, constitute an identifiable group, which, in theory, makes targeting them for PCC easier. The findings from the interview data and systematic review show a distinction between women with T1DM and women with T2DM that needs to be recognised so that effective allocation of care can be given at the right time and at the right level. Women with T1DM are most likely to be cared for within secondary specialist services, as they will have been referred there at diagnosis.



In the UK, women with T2DM are most likely to be cared for solely in primary care by their GP and the data presented above from the interviews and systematic review show a greater diversity of expertise within these settings. At the time of writing the responsibility for specialist care in England resides in CCGs, where primary and specialist services are commissioned. Such commissioners have to take into account NICE guidelines and quality standards but there is great variety in the range of services provided within GP practices and what falls within and outwith the remit of primary care. Whatever the level of expertise, it is incumbent on primary care practitioners who might comprise a single GP or a team of supporting service providers such as midwives, pregnancy planning experts and diabetes mellitus nurses, to meet the NICE guidelines in relation to the needs of women with diabetes mellitus for PCC. The level of care here is dependent on them recognising the need for PCC in order to mitigate the risks associated with diabetes mellitus and pregnancy. The findings of this study call into question whether or not the need for PCC for women with pre-existing diabetes mellitus is recognised fully within primary care settings.

In this study, we have identified a need for more training of GPs and midwives in relation to pregnancy and diabetes mellitus and also for all diabetes mellitus specialists in pregnancy planning. Furthermore, there is a gap in fertility services for women with diabetes mellitus who need fertility support and it should be recognised that, in the UK at least, many fertility service providers operate in the private sector.

Although a reconceptualisation of PCC answers the question of who should deliver care, it does not necessarily resolve the issue of when it should be offered. However, by recognising where women with T1DM and T2DM are receiving care it follows that these are the settings in which to offer support to women about pregnancy planning.

Responsibility for PCC could be enhanced by ensuring that:

- there is enhanced awareness training for the multidisciplinary health-care team to highlight the importance of diabetes mellitus in pregnancy and the significance of diabetes mellitus for women of childbearing age, especially within primary care settings
- NICE guidelines make clear who is responsible for providing elements of PCC to women with pre-existing diabetes mellitus.

### Quality of the relationship

Our data show that the relationship between women with diabetes mellitus and health-care professionals is integral to the success of any PCC, which places pregnancy planning and contraception at its core. The mixed reviews from women at interview and from the literature review highlight the extent to which a good relationship based on expert knowledge, partnership working and mutual respect affects its success. In practice, this translates into individualised care that allows for a coherent approach based on expert knowledge but one that sees women as individuals who each have unique circumstances. Furthermore, for this to be effective there needs to be continuity of care, which can be achieved through seeing the same carer(s) or at least effective communication of information between carers. Fundamental to effective care is the notion of a partnership model. Both the interview data and the review findings showed that for women to make a positive change they need to be respected as partners in their own care. This is echoed in the NICE guidelines<sup>14</sup> and is part of common wisdom in effective care in many conditions. Indeed, authoritarian or paternalistic approaches are more likely to lead to fear, resistance, resentment and ultimately to non-compliance with any guidance. There is a strong argument from the data that women want pregnancy to be a positive experience and not a fearful one in which they are anticipating the worst and in which they are expected to fail.

Furthermore, research on maternity services has highlighted the extent to which continuity of care, along with choice and control, matters to women and affects their experience of parenting. This applies even more so to women who are categorised as being at risk of complications through their diabetes mellitus status. Because of the level of risk, it is likely that their choices about pregnancy and birth and control over



the process will be limited and to some extent compromised, which makes continuity even more important to successful care.

The quality of relationships and the success of PCC could be enhanced by:

- further training for health professionals to support positive behaviour changes that focus on success, rather than the use of paternalistic and authoritarian approaches which focus on women's failure
- acknowledging to women that diabetes mellitus is disruptive to everyday life and that managing diabetes mellitus in pregnancy is hard work while normalising the experience of diabetes mellitus in pregnancy as much as possible
- recognising the importance of partnership models of care that include women's partners, families and wider social networks and environments.

## Strengths and limitations of the study

The study adopted a mixed-methods approach to explore why women with pre-existing diabetes mellitus of childbearing age do, or do not, access PCC. It also aimed to investigate the views of staff and stakeholders on existing and future provision of PCC. The study focused, in particular, on the facilitators of, and barriers to, the uptake of care with a view to informing services. The systematic view of the descriptive qualitative literature on this topic showed that previous research, with a few exceptions, had seldom focused on the facilitators of and barriers to uptake of care. In this project, qualitative research was carried out that focused specifically on exploring these issues and the analysis of the existing literature was carried out with this in mind.

The project originally intended to recruit 48 women with pre-existing diabetes mellitus to the research. Owing to a range of challenges, including difficulties with recruitment and R&D approval processes, only 12 women were recruited to the study. This level of recruitment to the study is a major limitation. Despite best efforts, recruitment was particularly challenging within primary care. Although the response rate to letters of invitation to participate in the study was acceptable (at 10%) there were difficulties in identifying women who met the inclusion criteria from patient databases and diabetes mellitus registers. As a result, additional recruitment measures were put into place including widening the study to other CCGs and initiating more practices than had been planned for initially. Face-to-face on-site recruitment was also explored, but no appropriate clinics could be identified. Given the low recruitment for the study, the study closed earlier than anticipated and the interviews with staff and stakeholders did not take place. The views of staff and stakeholders on PCC was therefore only explored through the systematic review. The challenges faced in recruiting from primary care are of note insofar as they highlight difficulties in identifying women with pre-existing diabetes mellitus (mainly T2DM) of childbearing age. It is interesting that the findings of this study highlight that diabetes mellitus in pregnancy is not always considered a priority within primary care and provision is likely to be inconsistent.<sup>36,41</sup>

Although low recruitment to the project is a significant limitation, the number of women recruited to the study is not atypical of similar types of qualitative study, including those reported in the systematic review.<sup>30,32,34,38</sup> Qualitative research does not seek to make statistical generalisations but to make generalisations of a theoretical or conceptual nature. It is important to note that the findings of the qualitative research in this study map favourably to the findings of the systematic review. For clarity, the findings of the systematic review and the qualitative research have been reported separately in each section as appropriate and together in the conclusions of this project.

## Implications for further research

Topics for further research include:

- Investigation of the views of stakeholders involved in the commissioning, design and delivery of pregnancy planning and PCC services for women with pre-existing diabetes mellitus.
- Further investigation of the views and experiences of minority and ethnically diverse groups, including the experiences of women who do not speak English.
- The role of family and other support in contraceptive use, pregnancy planning and PCC for women with pre-existing diabetes mellitus.
- The management of diabetes mellitus in neonatal care and its role in breastfeeding.

## Conclusions

The study findings suggest that there is a lack of clarity over what PCC for women with diabetes mellitus comprises and how it is perceived. The meaning and its boundaries are fluid. At its most fundamental it is about avoiding and/or mitigating the risks that pertain to diabetes mellitus and pregnancy. It follows from a more logical reconceptualisation of PCC that pregnancy planning, fertility and contraception are core elements of that care. This raises issues about the required levels of expertise needed for practitioners to deliver that care effectively.

The findings suggest that there is a lack of clarity about who is responsible for the delivery of PCC to women with diabetes mellitus and, if a reconceptualised model of PCC has pregnancy planning, fertility and contraception at its core, then this has a significant impact on whose responsibility delivery of PCC becomes. Furthermore, a distinction can be made between women with T1DM and women with T2DM as their care tends to be managed in different settings.

The study findings also indicate that the quality of that care delivery is dependent on a form of care that is based on partnership working, that is woman centred and that is individualised and values the need for continuity. Such care needs to be about enabling women to make changes that are positive rather than treating them as women at risk of failure. The success of any form of care will be dependent on good-quality care in all its elements.

We have argued that the first step in increasing the effectiveness of PCC to women with diabetes mellitus is to reconceptualise PCC as something that begins with effective pregnancy planning and contraception advice, including women with fertility needs.

It follows that the front-line workers who will enable women to make effective choices are those who women regularly consult for diabetes mellitus care. Identifying the points of care when any advice and interventions might be most effective requires health-care workers to be informed and up to date on contraception and diabetes mellitus. This might comprise a multidisciplinary team or the need for referral to specialist services. For women with T2DM this is most often in primary care whereas for women with T1DM it is likely to be in secondary care settings.

Any effective care needs to be within a relationship of respect and trust and the findings from this study support the NICE guidelines<sup>14</sup> that the relationship should be based on the principle of partnership. Furthermore, diabetes mellitus is a long-term condition that has associated complications for women's general health as well as increased risks during pregnancy. This makes continuity of care an important aspect of their health and well-being across the lifecourse.



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## Contributions of authors

**Sarah Earle** was principal investigator and grant holder. She supervised all aspects of the research, carried out the analysis of the systematic review and contributed to the qualitative data analysis. She led the drafting of the report. With **Cathy E Lloyd** she conceived the initial idea for the study, which was designed and developed with, **M Ali Karamat**, **Jackie Webb** and **Paramjit S Gill** who were all co-applicants on the project.

**Anisah Tariq** contributed to all aspects of the project including preparation of the study protocol, preparation for Research Ethics Committee review, recruitment of the sites in primary and secondary care, recruitment of interview participants and she conducted and transcribed all of the qualitative interviews. She also carried out the search for the systematic review and led the quality appraisal. She contributed to drafting the final report.

**Carol Komaromy** led the qualitative data analysis for the interview data and contributed to drafting the final report.

**M Ali Karamat** and **Jackie Webb** contributed to the recruitment of participants from secondary care.

**Paramjit S Gill** assisted with the recruitment of participants from primary care.

## Data sharing statement

A request for available data can be obtained via Open Research Online, the Open University's online repository: <http://oro.open.ac.uk>.



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# Appendix 1 'In/out' form used for systematic review: studies reporting women's experiences or perceptions

## Study reference

Date of review:

## Screening information

| Question   | Judgement   | Action required   |
|--|-------------|---|
| Is the study written in English?                                   | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study primarily report descriptive data?                  | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study include women of childbearing age?                  | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study focus on women's experiences or perceptions of PCC? | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study include women with pre-existing diabetes?           | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |

## Inclusion/exclusion decision

|         |         |                 |
|---------|---------|-----------------|
| Include | Exclude | Discuss with SE |
|---------|---------|-----------------|



## Appendix 2 'In/out' form used for systematic review: studies reporting practitioners' experiences or perceptions

### Study reference

Date of review:

### Screening information

| Question  | Judgement   | Action required   |
|---|-------------|---|
| Is the study written in English?  | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study primarily report descriptive data?                                   | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study refer to women of childbearing age?                                  | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study focus on practitioners' experiences or perceptions of providing PCC? | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |
| Does the study refer to women with pre-existing diabetes?                           | Y/N/unclear | If Yes – go to next question<br>If No – exclude<br>If unclear – discuss with SE |

### Inclusion/exclusion decision

|         |         |                 |
|---------|---------|-----------------|
| Include | Exclude | Discuss with SE |
|---------|---------|-----------------|



## Appendix 3 Citations of studies excluded after full review with reasons why they were excluded

| Study reference  | Reason for exclusion                        |
|--|---|
| Berg M. Pregnancy and diabetes: how women handle the challenges. <i>J Perinat Educ</i> 2005; <b>14</b> :23–32  | Does not focus on PCC                       |
| Berg M, Honkasalo ML. Pregnancy and diabetes – a hermeneutic phenomenological study of women's experiences. <i>J Psychosom Obstet Gynaecol</i> 2000; <b>21</b> :39–48  | Does not focus on PCC                       |
| Charron-Prochownik D, Sereika SM, Becker D, Jacober S, Mansfield J, White NH, <i>et al.</i> Reproductive health beliefs and behaviors in teens with diabetes: application of the Expanded Health Belief Model. <i>Pediatr Diabetes</i> 2001; <b>2</b> :30–9. <a href="http://dx.doi.org/10.1046/j.1399-543x.2001.00000.x">http://dx.doi.org/10.1046/j.1399-543x.2001.00000.x</a>         | Does not report descriptive data            |
| Charron-Prochownik D, Sereika SM, Falsetti D, Wang SL, Becker D, Jacober S, <i>et al.</i> Knowledge, attitudes and behaviors related to sexuality and family planning in adolescent women with and without diabetes. <i>Pediatr Diabetes</i> 2006; <b>7</b> :267–73. <a href="http://dx.doi.org/10.1111/j.1399-5448.2006.00197.x">http://dx.doi.org/10.1111/j.1399-5448.2006.00197.x</a> | Does not focus on women of childbearing age |
| Charron-Prochownik D, Sereika SM, Wang SL, Hannan MF, Fischl AR, Stewart SH, Dean-McElhinny T. Reproductive health and preconception counseling awareness in adolescents with diabetes: what they don't know can hurt them. <i>Diabetes Educ</i> 2006; <b>32</b> :235–42. <a href="http://dx.doi.org/10.1177/0145721706286895">http://dx.doi.org/10.1177/0145721706286895</a>            | Does not focus on women of childbearing age |
| Charron-Prochownik D, Ferons-Hannan M, Sereika S, Becker D. Randomized efficacy trial of early preconception counseling for diabetic teens (READY-girls). <i>Diabetes Care</i> 2008; <b>31</b> :1327–30. <a href="http://dx.doi.org/10.2337/dc07-1266">http://dx.doi.org/10.2337/dc07-1266</a>   | Does not report descriptive data            |
| Combs CA, Kitzmiller JL. Spontaneous abortion and congenital malformations in diabetes. <i>Baillieres Clin Obstet Gynaecol</i> 1991; <b>5</b> :315–31  | Does not report descriptive data            |
| Cruz J, Lang J, Márquez A. Control preconcepcional de la paciente diabética. <i>Revista Cubana de la Salud Publica</i> 2007; <b>33</b> . <a href="http://bvs.sld.cu/revistas/spu/vol33_4_07/spu10407.html">http://bvs.sld.cu/revistas/spu/vol33_4_07/spu10407.html</a>   | It is not in English                        |
| D'Angelo D, Williams L, Morrow B, Cox S, Harris N, Harrison L, <i>et al.</i> Preconception and interconception health status of women who recently gave birth to a live-born infant – Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 26 reporting areas, 2004. <i>MMWR Surveill Summ</i> 2007; <b>56</b> :1–35  | Does not report descriptive data            |
| Downs JS, Arslanian S, de Bruin WB, Copeland VC, Doswell W, Herman W, <i>et al.</i> Implications of type 2 diabetes on adolescent reproductive health risk: an expert model. <i>Diabetes Educ</i> 2010; <b>36</b> :911–19. <a href="http://dx.doi.org/10.1177/0145721710383586">http://dx.doi.org/10.1177/0145721710383586</a>   | Does not report descriptive data            |
| Evans MK, O'Brien B. Gestational diabetes: the meaning of an at-risk pregnancy. <i>Qual Health Res</i> 2005; <b>15</b> :66–81. <a href="http://dx.doi.org/10.1177/1049732304270825">http://dx.doi.org/10.1177/1049732304270825</a>   | Does not focus on pre-existing diabetes     |
| Hawthorne G. Preconception care in diabetes. <i>Semin Fetal Neonatal Med</i> 2005; <b>10</b> :325–32. <a href="http://dx.doi.org/10.1016/j.siny.2005.04.006">http://dx.doi.org/10.1016/j.siny.2005.04.006</a>  | Does not report descriptive data            |
| Hjelm K, Berntorp K, Frid A, Aberg A, Apelqvist J. Beliefs about health and illness in women managed for gestational diabetes in two organisations. <i>Midwifery</i> 2008; <b>24</b> :168–82. <a href="http://dx.doi.org/10.1016/j.midw.2006.12.008">http://dx.doi.org/10.1016/j.midw.2006.12.008</a>  | Does not focus on pre-existing diabetes     |
| Holmes VA, Spence M, McCance DR, Patterson CC, Harper R, Alderdice FA. Evaluation of a DVD for women with diabetes: impact on knowledge and attitudes to preconception care. <i>Diabet Med</i> 2012; <b>29</b> :950–6. <a href="http://dx.doi.org/10.1111/j.1464-5491.2012.03650.x">http://dx.doi.org/10.1111/j.1464-5491.2012.03650.x</a>   | Does not report descriptive data            |
| Janz NK, Herman WH, Becker MP, Charron-Prochownik D, Shayna VL, Lesnick TG, <i>et al.</i> Diabetes and pregnancy. Factors associated with seeking pre-conception care. <i>Diabetes Care</i> 1995; <b>18</b> :157–65  | Does not report descriptive data            |
| Kim C, Ferrara A, McEwen LN, Marrero DG, Gerzoff RB, Herman WH. Preconception care in managed care: the translating research into action for diabetes study. <i>Am J Obstet Gynecol</i> 2005; <b>192</b> :227–32   | Does not report descriptive data            |

| Study reference   | Reason for exclusion  |
|---|---|
| Lawrence JM. Women with diabetes in pregnancy: different perceptions and expectations. <i>Best Pract Res Clin Obstet Gynaecol</i> 2011; <b>25</b> :15–24. <a href="http://dx.doi.org/10.1016/j.bpobgyn.2010.10.003">http://dx.doi.org/10.1016/j.bpobgyn.2010.10.003</a>   | Does not report descriptive data                                    |
| Maharajan P, Duckitt K, Shah S, Liddie J. Pre-conception care in diabetes: where do we stand? <i>J Diabetes Nurs</i> 2010; <b>14</b> :30–4  | Does not report descriptive data                                    |
| Michel B, Charron-Prochownik D. Diabetes nurse educators and preconception counseling. <i>Diabetes Educ</i> 2006; <b>32</b> :108–16. <a href="http://dx.doi.org/10.1177/0145721705284371">http://dx.doi.org/10.1177/0145721705284371</a>  | Does not focus on women of childbearing age                         |
|   | Does not report descriptive data                                    |
| Mittal P, Dandekar A, Hessler D. Use of a modified reproductive life plan to improve awareness of preconception health in women with chronic disease. <i>Perm J</i> 2014; <b>18</b> :28–32. <a href="http://dx.doi.org/10.7812/TPP/13-146">http://dx.doi.org/10.7812/TPP/13-146</a>   | Does not report descriptive data.                                   |
| Moos MK. Preconceptional health promotion: progress in changing a prevention paradigm. <i>J Perinat Neonatal Nurs</i> 2004; <b>18</b> :2–13   | Does not focus on PCC for women with diabetes                       |
| Morgan MA, Hawks D, Zinberg S, Schulkin J. What obstetrician-gynecologists think of preconception care. <i>Matern Child Health J</i> 2006; <b>10</b> (Suppl. 5):59–65   | Does not focus sufficiently on diabetes                             |
|   | Lack of specificity in responses in relation to women with diabetes |
| Murphy HR, Roland JM, Skinner TC, Simmons D, Gurnell E, Morrish NJ, <i>et al</i> . Effectiveness of a regional prepregnancy care program in women with type 1 and type 2 diabetes: benefits beyond glycemic control. <i>Diabetes Care</i> 2010; <b>33</b> :2514–20. <a href="http://dx.doi.org/10.2337/dc10-1113">http://dx.doi.org/10.2337/dc10-1113</a> | Does not report descriptive data                                    |
| Rodgers BD, Rodgers DE. Efficacy of preconception care of diabetic women in a community setting. <i>J Reprod Med</i> 1996; <b>41</b> :422–6   | Does not report descriptive data                                    |
| Schwarz EB, Sobota M, Charron-Prochownik D. Perceived access to contraception among adolescents with diabetes barriers to preventing pregnancy complications. <i>Diabetes Educ</i> 2010; <b>36</b> :489–94  | Does not focus on women of childbearing age                         |
| Spence M, Harper R, McCance DR, Alderdice FA, McKinley MC, Hughes C, <i>et al</i> . The systematic development of an innovative DVD to raise awareness of preconception care. <i>European Diabetes Nursing</i> 2013; <b>10</b> :7–12b   | Does not report descriptive data                                    |
| Summers L, Price RA. Preconception care. An opportunity to maximize health in pregnancy. <i>J Nurse Midwifery</i> 1993; <b>38</b> :188–98   | Does not focus on PCC for women with diabetes                       |
| van Heesch PN, de Weerd S, Kotey S, Steegers EA. Dutch community midwives' views on preconception care. <i>Midwifery</i> 2006; <b>22</b> :120–4. <a href="http://dx.doi.org/10.1016/j.midw.2005.06.003">http://dx.doi.org/10.1016/j.midw.2005.06.003</a>  | Does not focus on PCC for women with diabetes                       |
| Varughese GI, Chowdhury SR, Warner DP, Barton DM. Preconception care of women attending adult general diabetes clinics – are we doing enough? <i>Diabetes Res Clin Pract</i> 2007; <b>76</b> :142–5. <a href="http://dx.doi.org/10.1016/j.diabres.2006.07.025">http://dx.doi.org/10.1016/j.diabres.2006.07.025</a>  | Does not report descriptive data                                    |
| Zeck W, Panzitt T, Schlembach D, Lang U, McIntyre D. Management of diabetes in pregnancy: comparison of guidelines with current practice at Austrian and Australian obstetric center. <i>Croat Med J</i> 2007; <b>48</b> :831–41  | Does not report descriptive data                                    |
| Zhu H, Graham D, Teh RW, Hornbuckle J. Utilisation of preconception care in women with pregestational diabetes in Western Australia. <i>Aust N Z J Obstet Gynaecol</i> 2012; <b>52</b> :593–6. <a href="http://dx.doi.org/10.1111/ajo.12010">http://dx.doi.org/10.1111/ajo.12010</a>  | Does not report descriptive data                                    |

## Appendix 4 Letter confirming favourable ethics opinion from National Research Ethics Committee

**NHS**  
**Health Research Authority**  
 NRES Committee South Central - Berkshire

05 March 2015

Dr Sarah Earle

Dear Dr Earle

**Study title:** Pre-conception care for women with type 1 or type 2 diabetes: What are the facilitators and barriers to uptake?  
**REC reference:** 15/SC/0026  
**IRAS project ID:** 156840

Thank you for your letter of 26 February 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Rae Granville, [nrescommittee.southcentral-berkshire@nhs.net](mailto:nrescommittee.southcentral-berkshire@nhs.net). Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

A Research Ethics Committee established by the Health Research Authority



**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

**Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.**

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

**Registration of Clinical Trials**

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact [hra.studyregistration@nhs.net](mailto:hra.studyregistration@nhs.net). The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

**Ethical review of research sites****NHS sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

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### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

| Document   | Version | Date             |
|--|---------|------------------|
| Covering letter on headed paper [Cover letter NREC]                            |         |                  |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)             |         |                  |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)             |         | 05 January 2015  |
| GP/consultant information sheets or letters [Letter to Patient GP]             | 1.0     | 22 December 2014 |
| GP/consultant information sheets or letters [Letter to GP (clean)]             | 2.0     | 13 February 2015 |
| GP/consultant information sheets or letters [Letter to GP tracked]             | 2.0     | 13 February 2015 |
| Interview schedules or topic guides for participants                           | 1.0     | 19 December 2014 |
| IRAS Checklist XML [Checklist_23122014]  |         | 23 December 2014 |
| IRAS Checklist XML [Checklist_27022015]  |         | 27 February 2015 |
| Letter from funder   | 1.0     |                  |
| Letters of invitation to participant [Letter from GP to patient - clean]       | 2.0     | 13 February 2015 |
| Letters of invitation to participant [Letter from doctor to patient - tracked] | 2.0     | 13 February 2015 |
| Letters of invitation to participant [Letter to stakeholders clean]            | 2.0     | 13 February 2015 |
| Letters of invitation to participant [Letter to stakeholders - tracked]        | 2.0     | 13 February 2015 |
| Other [Employers' Liability]   |         |                  |
| Other [Employers' Liability]   | 2.0     | 01 January 2015  |
| Other [New Cover Letter]   | 2.0     | 13 February 2015 |
| Other [Protocol v2.0 TRACKED]  | 2.0     | 04 February 2015 |
| Participant consent form [Consent Form Phase II v2.0 CLEAN]                    | 2.0     | 04 February 2015 |
| Participant consent form [Consent Form Phase II TRACKED CHANGES]               | 2.0     | 04 February 2015 |
| Participant consent form [Consent Form Phase III v2.0]                         | 2.0     | 04 February 2015 |
| Participant consent form [Consent Form Phase III v2.0 TRACKED]                 | 2.0     | 04 February 2015 |
| Participant consent form [Consent Form Phase IV v2.0 TRACKED CHANGES]          | 2.0     | 04 February 2015 |
| Participant consent form [Consent Form Phase IV CLEAN VERSION]                 | 2.0     | 04 February 2015 |
| Participant information sheet (PIS) [PIS Phase 2 v2.0 CLEAN]                   | 2.0     | 04 February 2015 |
| Participant information sheet (PIS) [PIS Phase II v2.0 TRACKED]                | 2.0     | 04 February 2015 |
| Participant information sheet (PIS) [PIS Phase III v2.0 CLEAN]                 | 2.0     | 04 February 2015 |
| Participant information sheet (PIS) [PIS Phase III v2.0 TRACKED]               | 2.0     | 04 February 2015 |
| Participant information sheet (PIS) [PIS Phase IV v2.0 TRACKED]                | 2.0     | 04 February 2015 |
| Participant information sheet (PIS) [PIS Phase IV v2.0 CLEAN]                  | 2.0     | 04 February 2015 |
| REC Application Form [REC_Form_23122014]                                       |         | 23 December 2014 |

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|   |     |                  |
|---|-----|------------------|
| Referee's report or other scientific critique report [NIHR Peer Review] |     |                  |
| Research protocol or project proposal                                   | 2.0 | 04 February 2015 |
| Summary CV for Chief Investigator (CI)                                  | 1.0 | 19 December 2014 |

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

### HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

<http://www.hra.nhs.uk/hra-training/>

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Please quote this number on all correspondence

A Research Ethics Committee established by the Health Research Authority

With the Committee's best wishes for the success of this project.

Yours sincerely



pp  
**Mr David Carpenter**  
Chair

Email: [Redacted]

*Enclosures:* "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

*Copy to:* **Mr Graham Mitchell, The Open University**  
**Ms Liz Adey, Heart of England NHS Foundation Trust**

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## Appendix 5 Recruitment letter sent to potential participants in primary care

<GP surgery Name/Clinic Name  
& Address>

<Date>

<Potential participant Name &  
Address>

Dear <Potential participant Name>,

**Name of study: Pre-conception Care for women with type 1 or type 2 diabetes: What are the facilitators and barriers to uptake?**

I am writing to invite you to participate in a research study being conducted at The Open University.

My colleagues, Dr Sarah Earle and Dr. Anisah Tariq from The Open University, are researching preconception care in pregnant women with diabetes. Their research study aims to gain a better understanding of the views of White British women and Pakistani women of childbearing age who have accessed pre-pregnancy care in the last 3 years and those that have not. This research is important because diabetes is the most common medical complication in pregnancy and because rates of diabetes are increasing. Also, if not managed well, diabetes in pregnancy can be harmful to health and this research aims to find out how better pregnancy planning could improve the health of women and babies.

As a care provider, I am involved in treating my patients and promoting research in order to understand and find better ways to treat medical conditions. I am not a member of the research team; however I am contacting you to let you know about the research in case you might be interested in learning more and getting involved.

It is important to know that this letter is not to tell you to join this study. It is your decision. Your participation is voluntary. Whether or not you participate in this study will have no effect on your relationship with <GP Practice/Heartlands Hospital> as a patient and will have no effect on your care with us.

If you are interested in learning more about this study, please review the enclosed **participant information sheet** from Dr. Anisah Tariq, complete the **enclosed form**, and mail it back to her in the pre-paid envelope provided. You can also contact the research team at [REDACTED] or [REDACTED]. You do not have to respond if you are not interested in this study. If you do not respond, no one will contact you, but you may receive another letter in the mail which you can simply disregard.

Thank you for your consideration.

Yours sincerely,

<GP/Clinician Name>

Enc: Participant Information Sheet v2.0 dated 04/02/15

Version 2.0

13/02/15

**Opt-IN Form****Preconception care for women with type 1 or type 2 diabetes**

The Open University

Please complete this form and return to Dr. Anisah Tariq in the pre-paid envelope provided.

OR

[Redacted]

I am interested in learning more about this study. Please contact me using the following information:

Name: \_\_\_\_\_

Telephone(s): \_\_\_\_\_

Best time and day to call: \_\_\_\_\_

Email: \_\_\_\_\_ @ \_\_\_\_\_

Return address: [Redacted]  
[Redacted]

# Appendix 6 Participant information sheet in English

REC Reference No: 15/SC/0026



## Pre-conception care for women with pre-existing diabetes

### PARTICIPANT INFORMATION SHEET

#### *We would like to invite you to participate in this original research study*

- You should only participate if you want to; choosing not to take part will not disadvantage you in any way.
- Regardless of your decision, your treatment and care will not be affected.
- Before you decide whether you want to take part in the research, it is important for you to understand why the research is being done and what your participation would involve.
- Please take time to read the information carefully and discuss it with family and friends if you wish.

#### *What is the study about?*

- The study aims to understand why women with pre-existing type 1 or type 2 diabetes of childbearing age, do, or do not, access pre-conception care.
- We want to hear about your views, your experience and your recommendations
- The study also aims to investigate the views of staff and other stakeholders with a view to exploring existing and future provision of pre-conception care services.

#### *What would taking part involve?*

- This will involve an interview at your home, or at another location if you prefer, and at a convenient time for you.
- The researcher will interview you for up to one hour and 15 minutes. All of the interviews will be audio recorded with your permission.
- You will be asked to answer questions about your experience of diabetes and your views on, or experiences of, pregnancy and pre-conception care.
- You will also be invited to participate in the next phase of the study (a focus group) but can choose not to, even if you agree to participate now.

#### *Why are we doing this research?*

- We are interested in this research because diabetes is the most common medical complication in pregnancy and rates of diabetes are increasing.
- Diabetes in pregnancy can be harmful to health if not managed correctly and this research project aims to find out how pregnancy planning could improve the health of women and babies.
- All members of the research team have a strong track record in carrying out health research and have experience of research in diabetes and reproductive care.

#### *How many will be involved in the study?*

- In this phase of the study we are hoping to recruit 24 White women and 24 Pakistani women who have either type 1 or type 2 diabetes and who have either accessed or not accessed pre-conception care.



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***Why have I been invited?***

- You have been invited to participate because you receive care at either Heartlands Hospital or have registered with a GP in Sandwell and West Birmingham area.; we are using different sites because different settings for care may influence women's experiences of their care and their access to it.
- You have been identified as eligible for the study by a member of your healthcare team.
- To participate you must be between 18 and 45 years of age and will be of white British origin, or Pakistani origin whose preferred language is not English.
- Rates of diabetes are increasing amongst White British and Pakistani women and Pakistani women have a particularly high risk of developing diabetes.
- There are high numbers of White British and Pakistani women who access pre-pregnancy and ante-natal care in Birmingham.

***Who are we excluding from the study?***

- Women under the age of 18 and over the age of 45.
- Unfortunately, we ask you *not* to participate if you have been diagnosed with a mental health problem.

***Who is organising and funding this research?***

- The study is being organised by a team of researchers at the Open University, The University of Birmingham and Heart of England NHS Trust.
- The Principle Investigator is Dr Sarah Earle, based at The Open University.
- The study is funded by the National Institute for Health Research (NIHR).

***Expenses and payments***

- Unfortunately we are unable to compensate you for your time in this study.
- We will travel to your choice of venue for the interview.

***What to expect during the consent process?***

- If you do decide to take part you will be asked to sign a consent form.
- The Research Associate (Dr Anisah Tariq) will take you through this form and answer any questions you have.
- Your participation in this study will not be affected should you choose not to be contacted again in the future.

***What are the advantages of taking part in the study?***

- You may enjoy taking part. You can also find useful information about diabetes and pre-conception care on the study website and you may want to contribute to the research blog.
- At the conclusion of the study, we will send you a newsletter describing the major findings and alerting you to any publications we have generated from the project.

***What if something goes wrong?***

- The risks involved in participating are minimal.
- If there are questions that you find upsetting or intrusive in any way, you are free to not answer them or to withdraw from participating, without giving a reason.

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***How will we maintain your privacy and confidentiality?***

- Everything you tell us will remain completely confidential within the limits of the law.
- We will give you a pseudonym and replace any information we have about you that could identify you.
- Your information will be stored on secure computers in locked offices and in locked filing cabinets.
- At the conclusion of the study, these data may be made available in totally anonymous form to other researchers outside of the project team. This means that, with your permission, the information you give us will be available to other researchers in the future. However, they will have no means of identifying you.
- The data generated from the project will be kept for ten years after which it will be destroyed securely.

***Involvement of General Practitioner (GP)***

- If you agree to participate we will inform your GP.

***What will happen if I don't want to carry on with the study?***

- It is up to you to decide whether to take part in the study or not.
- If you decide to take part you are still free to withdraw at any time and without giving a reason.

***Further information and contact details***

Ask us if anything is unclear or you would like more information.

If this study has harmed you in any way you can contact The Open for further advice and information:

**Thank you for reading this participant information sheet**



# Appendix 7 Participant information sheet in Urdu

REC Reference No: 15/SC/0026



## Pre-conception care for women with pre-existing diabetes

پہلے سے موجود ذیابیطس والی خواتین کے لئے حاملہ ہونے سے پہلے دیکھ بھال

### PARTICIPANT INFORMATION SHEET

حصہ لینے والوں کے لئے معلوماتی پرچہ

ہم آپ کو اس اہدائی تحقیقی مطالعہ میں حصہ لینے کی دعوت دنا چاہتے ہیں

- آپ کو صرف اس صورت میں حصہ لینا پڑے گا اگر آپ پابندی میں: حصہ لینے کا انتخاب کرنا آپ کے لئے کسی طریقے سے بھی غیر مناسب نہیں ہوگا۔
- آپ کے فیصلے کے تحت نظر، آپ کا علاج معالجہ اور دیگر بھال متاثر نہیں ہوگی۔
- اس سے پہلے کہ آپ تحقیق میں حصہ لینے کا فیصلہ کریں، آپ کے لئے سمجھنا ضروری ہے کہ تحقیق کیوں کی جارہی ہے اور آپ کے حصہ لینے میں کیا کچھ شامل ہوگا۔
- ہر لوگ کم معلومات کو امتیاز سے پڑھنے کے لئے وقت نکالیں اور اگر آپ پابندی میں تو اس پر غور کرنا ہے اور دوست و احباب سے تبادلہ خیال کریں۔

مطالعہ کی پیچیدگی کے بارے میں ہے؟

- مطالعہ کا مقصد اس بات کو سمجھنا ہے کہ پہلے سے موجود ٹائپ 1 اور ٹائپ 2 ذیابیطس والی خواتین کو پیچیدگی سے نمٹنے کی ضرورت ہے، حاملہ ہونے سے پہلے دیکھ بھال تک رسائی حاصل کرتی ہیں، یا نہیں حاصل کرتیں۔
- ہم آپ کی رائے، آپ کے تجربات اور معلومات پانا چاہتے ہیں۔
- مطالعہ کا مقصد یہ بھی ہے کہ جیسے اور دوسرے دلچسپ رکھنے والوں کی رائے کی اس نظریہ کے ساتھ تحقیقات کی جائیں تاکہ حاملہ ہونے سے پہلے کی دیکھ بھال کی سرسوزی اور مسائل میں فراہمی کی کمیوں کو مٹایا جاسکے۔

حصہ لینے میں کیا کچھ ملوث ہوگا؟

- اس میں آپ کے گھر پر یا اگر آپ باہر تو کسی اور جگہ پر، آپ کے لئے ایک سہولت مدت پر ایک انٹرویو شامل ہوگا۔
- تحقیق کرنے والے (ریسرچر) ایک محفل 15 منٹ تک آپ کا انٹرویو کرے گا۔ آپ کی اہلیت کے ساتھ تمام انٹرویوز کی آٹو ریکارڈنگ کی جائے گی۔
- آپ سے کہا جائے گا کہ آپ ذیابیطس کے بارے میں اپنے تجربات کے بارے میں سوالوں کے جواب دیں اور حاملہ اور حاملہ ہونے سے پہلے دیکھ بھال پر اپنی رائے، یا اپنے تجربات کا اظہار کریں۔
- آپ کو مطالعہ کے اگلے مرحلے میں بھی حصہ لینے کی دعوت دی جائے گی (ایک فوکس گروپ) لیکن آپ حصہ لینے کا فیصلہ کر سکتی ہیں، یا اسے اگر آپ اس میں حصہ لینے سے انکار کر دیں۔

ہم یہ تحقیق کیوں کر رہے ہیں؟

- ہم اس تحقیق میں دلچسپی رکھتے ہیں کیونکہ ذیابیطس حاملہ ہونے میں سب سے عام طبی پیچیدگی ہے اور ذیابیطس کی شرح بدھ رہی ہے۔
- حاملہ ہونے کے دوران ذیابیطس صحت کے لئے نقصان دہ ہو سکتی ہے اگر اس کا درست طریقے سے انتظام نہیں کیا جائے یا اگر اس تحقیقی پراجیکٹ کا مقصد یہ جاننا ہے کہ حاملہ ہونے کے دوران منصوبہ بندی سے کس طرح سے خواتین اور بچوں کی صحت کو بہتر بنایا جاسکتا ہے۔
- تحقیق کرنے والی ٹیم کے تمام اراکین کا مقصد کے بارے میں تحقیق کرنے کا ایک منصوبہ سمجھنا ہے تاکہ وہ دیکھا جائے اور انہیں ذیابیطس اور نسلی تسلسل کی دیکھ بھال میں تحقیق کا تجربہ ہے۔

اس مطالعہ میں کتنے لوگ شامل ہوں گے؟

- مطالعہ کے اس مرحلے میں ہم امید کرتے ہیں کہ کم از کم 24 سفید فام (White) خواتین اور 24 پاکستانی (Pakistani) خواتین بھرتی کریں جنہیں یا تو ٹائپ 1 یا ٹائپ 2 ذیابیطس ہے اور جنہوں نے یا تو حاملہ ہونے سے دیکھ بھال تک رسائی حاصل کی ہے یا نہیں حاصل کی ہے۔

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### مجھے دعوت کب دی گئی ہے؟

- آپ کو صبر لینے کی دعوت اس لئے دی گئی ہے کیونکہ آپ یا توہارت لیڈز ہسپتال (Heartlands Hospital) سے دیگر بھال ماسل کرتی ہیں یا آپ سینڈ ویل (Sandwell) اور ولسٹ بر سٹیم (West Birmingham) علاقے میں ہی پی (GP) کے پاس رجسٹرڈ ہیں، ہم صحت نگہیں استعمال کر رہے ہیں کیونکہ ہو سکتا ہے کہ دیگر بھال کے لئے صحت نگہیں ماسل خواہین کی دیگر بھال کے تجربات اور اس تک ان کی رسائی پر اثر انداز ہوئے ہوں۔
- آپ کی صحت کی دیگر بھال کی ہم کے ایک رکن نے آپ کی مطالعہ کے لئے اہل ہونے کی حیثیت سے نظر دے دی ہے۔
- صبر لینے کے لئے آپ کی عمر لازماً 18 اور 45 سال کے درمیان ہونی چاہئے اور آپ صبر نام برطانوی (British) بھال، پاکستانی (Pakistani) بھالوں میں سے کسی ایک زبان انگریزی (English) نہیں ہے۔
- صبر نام برطانوی (White British) اور پاکستانی (Pakistani) خواہین میں فیاضیت کی شرح بدھ رہی ہے اور پاکستانی (Pakistani) خواہین کو خاص طور پر فیاضیت ہو جانے کا بہت زیادہ خطرہ ہے۔
- بر سٹیم (Birmingham) میں بہت زیادہ تعداد میں ایسی صبر نام برطانوی (White British) اور پاکستانی (Pakistani) خواہین ہیں جو حاملہ ہونے سے پہلے اور بچے کی پیدائش سے پہلے کی دیگر بھال تک رسائی حاصل کرتی ہیں۔

### ہم کے مطالعہ میں شامل نہیں کر رہے ہیں؟

- ایسی خواہین جن کی عمر 18 سال سے کم ہے اور 45 سال سے زیادہ ہے۔
- بد قسمتی سے، اگر آپ کی دائمی صحت کے مسئلے کے لئے تشخیص ہوئی ہے تو ہم آپ سے نہیں کے کہ آپ صبر نہ لیں۔

### اس تحقیق کا انتظام اور مالی مدد کون کر رہا ہے؟

- مطالعہ کا انتظام ایون یونیورسٹی، دی یونیورسٹی آف بر سٹیم (Open University, The University of Birmingham) اور ہارت آف انگلینڈ اینڈ ایلز ٹرسٹ (Heart of England NHS Trust) کی تحقیق کرنے والوں کی ایک ٹیم کر رہی ہے۔
- پرنسپل ایجنٹ (Principal Investigator) کرنے والی میں ڈاکٹر سارہ ایل (Dr Sarah Earle)، دی یونیورسٹی آف بر سٹیم (The Open University) میں محکم ہیں۔
- مطالعہ کی مالی مدد نیشنل انسٹی ٹیوٹ فار ہیلتھ ریسرچ [این آئی اے آر] (National Institute for Health Research (NIHR)) نے کی ہے۔

### اوقات اور لواحقین

- بد قسمتی سے ہم اس مطالعہ میں آپ کو آپ کے وقت کے لئے معاوضہ نہیں دے سکتے۔
- شرط کے لئے ہم آپ کی ہمدردی بک رہا ہیں گے۔

### رہنمائی عمل کے دوران کیا توقع کیا جاسکتا ہے؟

- اگر آپ صبر لینے کا فیصلہ کرتی ہیں تو آپ سے کہا جائے گا کہ آپ ایک رہنمائی فارم پر دستخط کریں۔
- تحقیق میں ساتھی (Research Associate) [ڈاکٹر انیسہ طارق] (Dr Anisah Tariq) آپ کو یہ فارم واضح کریں گی اور آپ کے کسی سوالوں کا جواب دیں گی۔
- اگر آپ مستقبل میں دوبارہ رابطہ نہ کرنے کا انتخاب کرتی ہیں تو اس مطالعہ میں آپ کا صبر لینا اس پر اثر انداز نہیں ہو گا۔

### اس مطالعہ میں صبر لینے کے کیا فوائد ہیں؟

- ہو سکتا ہے کہ آپ صبر لینے سے صحت مند ہوں۔ آپ مطالعہ کی ویب سائٹ پر فیاضیت کے بارے میں صبر معلومات بھی تلاش کر سکتی ہیں اور ہو سکتا ہے کہ آپ تحقیقاتی باک میں مدد کرنا چاہیں۔
- مطالعہ کے اختتام کے بعد، ہم آپ کو ایک ہیڈ لائنر بھیجیں گے جس میں پڑی ماسل ہونے والی معلومات کی تفصیل ہوگی اور جس سے پرائیکٹ سے اگر کوئی اثاثہ ہوئی ہو تو آپ کو ان کے بارے میں اطلاع دیں گے۔

### اگر کچھ غلط ہو گیا تو پھر کیا ہو گا؟

- صبر لینے کے لئے شامل ہونے کے خطرات بہت کم ہیں۔
- اگر کوئی ایسے سوالات ہیں جنہیں آپ کسی بھی طریقے سے پرائیڈن یا مدافعت کرنے والا نہیں، تو آپ آواز دیں کہ آپ ان کا جواب نہ دیں یا کوئی وجہ بتانے کے بغیر صبر لینے سے دست بردار ہو جائیں۔

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ہم آپ کی پیشگی اور رازداری کو بھیجے قائم رکھیں گے؟

- آپ ہیں، پھر بھی ہمیں کی وہ قانون کی مدد کے اندر بالکل رازدار ہے گا۔
- ہم آپ کو ایک فرضی نام دیں گے اور آپ کے بارے میں جانے کسی ایسی معلومات کو تبدیل کر دیں گے جن سے آپ کی شناخت ہو سکتی ہے۔
- آپ کی معلومات کو محفوظ کیونکہ ہر تالے دار دقت میں اور تالے دار قفل کی تلاش میں سہولت کیا جائے گا۔
- مطالعہ کے اختتام پر ہو سکتا ہے کہ ان معلومات [ڈیٹا] کو بالکل مکمل شکل میں پرائیکٹ ٹیم سے باہر منتقل کرنے والوں کو فراہم کیا جائے۔ اس کا مطلب ہے کہ آپ کی اہلیت کے ساتھ، آپ ہیں، معلومات دیں گے وہ مشکل میں دوسرے منتقل کرنے والوں کے لئے دستیاب ہوں گی۔ ہم، آپ کی شناخت کرنے کے لئے ان کے پاس کوئی ذرائع نہیں ہوں گے۔
- پرائیکٹ سے حاصل ہونے والی معلومات [ڈیٹا] کو دس سال تک رکھا جائے گا جس کے بعد اسے محفوظ طریقے سے خارج کر دیا جائے گا۔

جنرل پریکٹیشنر [جی پی] (General Practitioner (GP)) کا رول ہے

- اگر آپ صر لینے سے اتفاق کرتی ہیں تو پھر ہم آپ کے رکی جی پی (GP) کو آگاہ کریں گے۔

اگر میں مطالعہ کو جاری نہیں رکھا جائی تو پھر کیا ہو گا؟

- اس بات کا فیصلہ آپ کو کرنا ہے کہ کیا آپ مطالعہ میں صر لینا چاہتی ہیں یا نہیں۔
- اگر آپ صر لینے کا فیصلہ کرتی ہیں تو پھر بھی آپ آزاد ہیں کہ آپ کسی بھی وقت کوئی وجہ بتلے کے بغیر دست بردار ہو جائیں۔

مزید معلومات اور رابطہ تفصیلات

اگر کوئی توجہ خواہش ہے یا آپ مزید معلومات حاصل کرنا چاہتی ہیں تو ہم سے پوچھیں۔

بروکرم ڈاکٹر سارا ایل (Dr Sarah Earle) سے بذریعہ ای میل [Redacted] یا رابطہ کریں، بذریعہ فون [Redacted] یا بذریعہ ڈاک اس پتہ پر: [Redacted]  
Faculty of Health and Social Care, The Open University, Walton Hall, Milton Keynes, MK7 6AA.

اگر اس مطالعہ سے آپ کو کسی بھی طرح نقصان پہنچا ہے تو آپ دی اوپن (The Open) سے مزید مشورے اور معلومات کے لئے رابطہ کر سکتے ہیں: سربیری روج (Mr Jeremy Roche):  
[Redacted] آپ اپنے مقامی این ایچ ایس ریسرچ اینڈ ڈیولپمنٹ آفس NHS Research & Development Office سے بھی، 0121 424 1633 یا رابطہ کر سکتی ہیں۔

صر لینے والوں کے لئے اس معلوماتی پے کو پڑھنے کے لئے آپ کا شکریہ۔



## Appendix 8 Interview topic guide

### Interview Topic Guide: Pre-conception care for women with pre-existing diabetes

- **Introduction to interview** (explain process of interview, discuss consent and recording of interview, invite participant to ask questions)
- **Experience of diabetes** (incl. type of diabetes, when diagnosed/how long ago, treatment, changes to treatment in relation to pregnancy (if relevant), care received)
- **Pregnancy history** (incl. parity, pregnancy complications, experiences of diabetes in pregnancy, management of diabetes, care received)
- **Obstetric history** (if parous) (incl. type of delivery, obstetric complications, management of diabetes)
- **Pregnancy planning** (incl. explore pregnancy intention, pregnancy preparation, role of others, information and advice received/sought)
- **Contraception** (incl. contraceptive use, contraceptive decision-making, information and advice on contraception, changes to contraception re diabetes, influences on contraceptive choices, care received)
- **Pre-conception advice and care** (incl. whether PCC used/likely to be used and reasons why, experiences of PCC (if relevant), knowledge and understanding of PCC, influences on PCC, monitoring of blood glucose levels, care received, ask specifically about barriers and facilitators to PCC)
- **Demographic information and end interview** (check demographic information not already captured and invite participant to ask questions or to discuss/clarify issues)

v1.0 April 2015





# Appendix 9 Participant consent form in English

NIHR Study Number: 12/185/14

REC reference Number: 15/SC/0026



## CONSENT FORM (phase II)

Title of Project: **Pre-conception Care for Women with Diabetes**

Name of Researcher: Dr **Anisah** Tariq

Please initial box

1. I confirm that I have read the information sheet dated 4<sup>th</sup> February 2015 (version2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected and that if I withdraw none of my data will be used in the study.
3. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers, and that it will be stored securely for 10 years.
4. I understand that my real name will not be used in the study and my personal information will not be revealed to people outside of the study.
5. I understand that my words may be quoted in publications, reports, web pages and other research outputs.
6. I agree to my General Practitioner being informed of my participation in the study.
7. I understand that agreeing to take part in the study means that I will be audio-recorded.
8. I agree to take part in the above study.
9. I agree to be contacted about participation in the next phase of the study.

☐
☐
☐
☐
☐
☐
☐
☐
☐

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed: 1 for participant; 1 for researcher site file (original).  
Version 2.0 – Phase II

04/02/15



# Appendix 10 Participant consent form in Urdu

NIHR Study Number: 12/185/14

REC reference Number: 15/SC/0026



## رضامندی فارم [فیز 11] (phase II) CONSENT FORM

پرائیویٹ کا محفل: فیاض علی خواجہ کے لئے ماہر ہونے سے پہلے دیکھ بھال Pre-conception Care for Women with Diabetes

تحقیق کرنے والے / واپس کا نام: ڈاکٹر انیسہ طارق Dr Anisah Tariq

براہ کرم نام لکھنے میں اٹھان لکھیں

☐

1. میں تصدیق کرتی ہوں کہ درج بالا مطالعہ کے لئے میں نے معلوماتی پروپوزل 4 فروری 2015 [فرز 2.0] پڑھ لیا ہے۔ مجھے صریح ہے کہ میں معلومات پر غور کر سکوں، سوالات پوچھ سکوں اور ان کا اطمینان بخش جواب حاصل کر سکوں۔

☐

2. میں سمجھتی ہوں کہ میرا اصل دیکھ بھال یہ ہے اور میں کسی بھی وقت کوئی بھی دہرے جانے کے بغیر دست بردار ہو سکتی ہوں، میری طبی دیکھ بھال یا قانونی حقوق پر کسی اثر پڑنے کے بغیر اور یہ کہ اگر میں دست بردار ہوتی ہوں تو مطالعہ میں میرے بارے میں کسی بھی معلومات [ذخا] کو استعمال نہیں کیا جائے گا۔

☐

3. میں سمجھتی ہوں کہ میرے بارے میں انہی کی جانے والی معلومات کو مستعمل میں کی جانے والی دیگر تحقیق میں استعمال کیا جائے گا، اور ہو سکتا ہے کہ اسے نام کے بغیر دوسرے تحقیق کرنے والوں کے ساتھ ان میں تقسیم کیا جائے، اور یہ کہ اسے 10 سالوں کے لئے محفوظ طریقے سے محفوظ کیا جائے گا۔

☐

4. میں سمجھتی ہوں کہ میرے اصل نام کو مطالعہ میں استعمال نہیں کیا جائے گا اور میری ذاتی معلومات کا مطالعہ سے باہر کے لوگوں کو نکالتا نہیں کیا جائے گا۔

☐

5. میں سمجھتی ہوں کہ ہو سکتا ہے کہ میرے الفاظ کا اٹھا مل، رپورٹوں، صوبے کے صفحات اور دیگر تحقیقی مجموعوں میں وارد کیا جائے۔

☐

6. میں اتفاق کرتی ہوں کہ میرے بزل پر پبلشر کو میرے مطالعہ میں حصہ لینے کے بارے میں آگاہ کیا جائے۔

☐

7. میں سمجھتی ہوں کہ مطالعہ میں حصہ لینے کا مطلب ہے کہ میری آڈیو ریکارڈنگ کیا جائے گا۔

☐

8. میں درج بالا مطالعہ میں حصہ لینے سے اتفاق کرتی ہوں۔

☐

9. میں اتفاق کرتی ہوں کہ مطالعہ کے اگلے مرحلے میں حصہ لینے کے لئے مجھے دوبارہ دیکھا جائے۔

Name of Participant

تاریخ

دستخط

Name of Person taking consent

تاریخ

دستخط

رضامندی حاصل کرنے والے فرد کا نام

When completed: 1 for participant; 1 for researcher site file (original).  
Version 2.0 – Phase II

04/02/15



# Appendix 11 Useful information sheet for participants

## PCC Pre-conception care for women with diabetes



The Open University

# Useful Information

On behalf of the research team, thank you for taking part in our study!  
If you feel you need more information or support, please contact your healthcare team or take a look at the useful resources below.

| Service provided | Patient Advice and Liaison Service (PALS) at Heart Of England NHS Foundation Trust  |
|------------------|---|
| Description      | PALS has been introduced to ensure that the NHS listens to patients, their relatives, carers and friends, and answers their questions and resolves their concerns as quickly as possible. PALS also helps the NHS to improve services by listening to what matters to patients and their loved ones and making changes, when appropriate. |
| Telephone number | 0121 424 0808<br>9am – 4.30pm (Monday to Thursday) and 9am – 4pm (Friday)   |
| Address          | Bordesley Green East, Bordesley Green, Birmingham, West Midlands, B9 5SS  |
| Email address    | <a href="mailto:patientservices@heartofengland.nhs.uk">patientservices@heartofengland.nhs.uk</a>  |

### NICE website

(<http://publications.nice.org.uk/diabetes-in-pregnancy-ifp63>) provides:

- Information on diabetes in pregnancy

Our **PCC website** ([www.open.ac.uk/pcc](http://www.open.ac.uk/pcc)) provides:

- Information about the project
- Links to other resources on pre-existing diabetes in pregnancy
- Links to relevant service user groups on pre-conception care, diabetes and pregnancy
- A blog where service users and providers can post comments
- Progress reports of the project

### Diabetes UK website

(<http://www.diabetes.org.uk/Guide-to-diabetes/Living-with-diabetes/Pregnancy/>) provides:

- Advice from pre-conception ... to after the birth.

### NHS Choices Diabetes and Pregnancy website

(<http://www.nhs.uk/Conditions/pregnancy-and-baby/Pages/diabetes-pregnant.aspx#close>) provides:

- Useful information and articles
- Internal and external links
- Pregnancy planning toolkit
- Search for NHS services near you

Version 2.0 February 2015







A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and flow.

EME  
HS&DR  
**HTA**  
PGfAR  
PHR

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